

Automatic Identification Data Capture (AIDC)

Requirements Specification DAPB0108 Amd 1/2022

April 2022

**Improving lives with
data and technology**

Data Alliance Partnership Board

The Data Alliance Partnership Board (DAPB), which holds delegated authority from the Secretary of State for Health and Social Care, has approved a change to an existing information standard for publication under [section 250 of the Health and Social Care Act 2012](#).

Assurance that this information standard meets the requirements of the Act and is appropriate for the use specified in the specification document has been provided by the Data Standards Assurance Service (DSAS) and endorsed by the Data Alliance Partnership Sub Board (DAPSB).

This information standard comprises the following documents:

- Change Specification
- Implementation Guidance
- Requirements Specification.

An Information Standards Notice (DAPB0108 Amd 1/2022) has been issued as a notification of use and implementation timescales. Please read this alongside the documents for the standard.

The controlled copies of these documents can be found on the [NHS Digital website](#). Any copies held outside of that area, in whatever format (e.g. paper, email attachment), are considered to have passed out of control and should be checked for currency and validity.

Date of publication: 14 April 2022

Copyright © 2022 NHS Digital

NHS Digital permits the copying and re-use of Information Standards, in whole or in part, for commercial and non-commercial purposes but, to protect the integrity of the Information Standards, you are not permitted to adapt, amend or decompile the Information Standards for any purpose without our prior consent.

The third-party content covering GS1 UK Limited methodologies and products remains the copyright of GS1 UK Limited.

If you have any queries on the copyright of this information standard please contact standards.assurance@nhs.net

Contents

1	Glossary of Terms	5
2	Supporting Information	8
2.1	Related Standards	8
2.2	Supporting Guidance	8
3	Overview	9
4	Concept of Use	12
4.1	GS1 Standards	12
4.2	GS1 Standards Management Process (GSMP)	12
4.3	GS1 and ISO/IEC Standards	12
4.4	GS1 General Specifications	12
4.5	GS1 Membership	13
5	Requirements	14
5.1	Information Specification	14
5.2	Conformance Criteria	16
6	Legal Position of GS1	18
7	GS1 Identification Standards	19
7.1	GS1 Company Prefix (GCP)	19
7.2	GS1 Identification Keys	19
7.3	GS1 Application Identifiers	41
7.4	Data Relationships	42
8	GS1 Data Carriers	45
8.1	GS1 DataMatrix	45
8.2	GS1-128	47
8.3	EAN-13	49
8.4	Radio Frequency Identification (RFID)	51
8.5	Data Carrier Management	53
9	Barcode Production	56
9.1	Choosing the Right Data Carrier	56
9.2	Printing Considerations	58
10	Data Carrier Quality and Compliance	59
10.1	Barcode Validation	59

10.2	Barcode Verification	59
10.3	RFID Tag Validation	61
10.4	Validation and verification support for NHS Trusts	61

11	Helpdesk	63
-----------	-----------------	-----------

11.1	Contact Information	63
11.2	Useful Resources	63

12	Appendices	64
-----------	-------------------	-----------

Appendix 1:	My Numberbank	64
Appendix 2:	The GS1 Subset of International Standard ISO/IEC 646	65
Appendix 3:	Check Digit	67
Appendix 4:	Function 1 (FNC1) Symbol Character	68
Appendix 5:	Element Strings with Predefined Length	69
Appendix 6:	Linear Barcode Orientation	70
Appendix 7:	LocationManager	71

1 Glossary of Terms

Term	Definition
2D barcode	Two-dimensional barcodes are optically readable barcode symbols that must be examined both vertically and horizontally, in two dimensions, to read the entire message.
AIDC	Automatic Identification and Data Capture is a category of technologies used to identify and capture data automatically, without human involvement and includes technologies such as barcodes and RFID, widely known as data carriers, as well as the scanners, printers, software and systems used to produce, read and manage data carriers.
Application identifier (AI)	The GS1 Application Identifier is the field of two, three or four digits at the beginning of an element string that uniquely defines its format and meaning.
Attribute	A piece of information reflecting a characteristic related to a GS1 Identification Key, for example, a batch number or expiry date associated with a Global Trade Item Number (GTIN).
Barcode	Barcodes are symbols which are encoded with data in a machine-readable pattern. They can be either a 1D (linear) or 2D format and are read with either laser or camera-based scanners, respectively. Barcodes are also known as optical data carriers.
Basic UDI-DI	Basic Unique Device Identifier – Device Identifier, is the main key for medical device records in the UDI regulatory database and identifies a product model or family. Implementation of the Basic UDI-DI as required by the Medicines and Healthcare products Regulatory Agency (MHRA) , is supported by the GS1 Identification Key Global Model Number (GMN).
Check character pair	A final character pair calculated from the other characters of the Global Model Number. Used to check that data has been correctly composed and transmitted.
Check digit	A numeric character calculated from data and appended as part of the data string to ensure that the data is correctly composed and transmitted.
Data carrier	Any medium that can record and convey data in a machine-readable format. Barcodes and EPC/RFID tags are two different data carrier types.
Data titles	Data titles are the standard abbreviated descriptions of element strings, used to support the manual interpretation of encoded data.
DAPB	The Data Alliance Partnership Board has replaced the Data Coordination Board (DCB) and has taken over its function to approve information standards, data collections and extractions (ISCEs).
Element string	The combination of a GS1 Application Identifier and the data that follows. Also known as a data string.
Electronic Product Code (EPC)	An identification scheme for universally identifying physical objects (e.g., trade items, assets, and locations) via RFID tags and other means.
Function 1 (FNC1)	A symbology character used to provide special operation and application instructions to barcode reading devices (i.e., scanners).
GCP	GS1 Company Prefix is used exclusively within GS1 identification standards and is a unique string of four to twelve digits used to issue GS1 Identification Keys. GCPs assigned to a member of any GS1 Member Organisation e.g., GS1 UK, and entitles that member to create any of the GS1 Identification Keys.

Term	Definition
GDTI	Global Document Type Identifier is the GS1 Identification Key used to identify a document type.
GIAI	Global Individual Asset Identifier is the GS1 Identification Key used to identify an individual asset.
GLN	Global Location Number is the GS1 Identification key which used to identify any type of location and party used in business processes.
GRAI	Global Returnable Asset Identifier is the GS1 Identification Key used to identify returnable assets.
GS1	The governing body for GS1 member organisations which administers the GS1 system. GS1 a not-for-profit organisation that develops and maintains global standards for business communication.
GS1 Identification Key	A globally unique and unambiguous primary identifier for a class of objects (e.g., a trade item) of an object (e.g., logistic unit).
GSRN	Global Service Relation Number is the GS1 Identification Key used to identify the relationship between an organisation offering services and the recipient or provider of services.
GTIN	Global Trade Identification Number is the GS1 Identification Key used to identify trade items or traded services.
Human readable interpretation (HRI)	Human readable interpretation is the encoded data, including GS1 AIs shown with parentheses, presented in a human readable format. HRI is usually visible in an area beneath or near the barcode.
ISO/IEC	International Organisation for Standardisation and International Electrotechnical Commission are a joint technical committee that develop and maintain international standards related to information technology for business and consumer applications.
Linear (1D) barcode	Barcode symbology using bars and spaces in one dimension.
Module	The narrowest nominal width unit of measure in a barcode. The nominal width (& height for 2D barcodes) of a single module is equivalent to the X-dimension
Quiet zone	A clear space which precedes the start character and follows the stop character of a linear barcode or surrounds a 2D symbol.
RFID	Radio Frequency Identification is the technology that uses radio frequency electromagnetic fields or waves to automatically identify, and track tags attached to objects. An RFID system consists of RFID tags and readers. When triggered by a radio frequency electromagnetic interrogation signal from a nearby RFID reader, the RFID tag transmits digital data, usually a unique identifier like an EPC, back to the reader, without any direct line of sight required.
RFC 2119	A best practice document by the Internet Engineering Task Force (IETF) which defines conformance keywords (MUST, SHOULD, MAY) that are used in specifications, to indicate requirement levels.
SSCC	Serial Shipping Container Code is the GS1 Identification Key used to identify logistics units.
Symbology identifier	A 3-character data string that is not encoded to a barcode but is generated when decoding a barcode and transmitted as a preamble to the data. This enables scanning equipment to recognise the symbology type and, in the case of GS1 barcodes, enables the data to be understood and processed in accordance with GS1 Standards.

Term	Definition
UDI-DI	Unique Device Identifier – Device Identifier, identifies a medical device as required by the Medicines and Healthcare products Regulatory Agency (MHRA) , and is supported by the GS1 Identification Key Global Trade Item Number (GTIN).
X dimension	The specified width of the narrowest element of a barcode (see module).

2 Supporting Information

2.1 Related Standards

Related Standards MUST be used and read alongside this document.

Reference ¹	Title (including links)
Release 21.0.1	GS1 General Specifications
Release 2.5.1	GS1 DataMatrix Guidelines
Release 10.0	GS1 Healthcare GTIN Allocation Rules
Release 3.0.1	GS1 GLN Allocation Rules Standard
Release 1.13	GS1 EPC Tag Data Standard
ISB 0149	NHS Number
DCB0160	Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems
DCB0129	Clinical Risk Management: its Application in the Manufacture of Health IT Systems

2.2 Supporting Guidance

Supporting Guidance MAY be used and read alongside this document.

Reference ¹	Title (including links)
ISBT-128	ICCBBA technical standard for the identification, labelling and information processing of medical products of human origin
DCB1077	AIDC for Patient Identification
March 2021	GS1 UK Surgical Instrument Traceability Guidance
Release 2.1	GS1 Healthcare GLN Implementation Guideline
Release 1.1	GS1 Identification of Investigation Products in Clinical Trials Application Standard
Release 1.3	GS1 Logistics Label Guideline
Release 1.0	GS1 Guidelines for the distribution and shipping of medical product of human origin (MHRO)
Release 2.1	GS1 EPC UHF Gen2 Air Interface Protocol Standard
Version 2.0.3	GS1 EPC Class-1 HF RFID Air Interface Protocol Standard

¹ GS1 General Specifications and GS1 Standards documents are updated regularly, so whilst release/version numbers or date references have been provided here, the link provided will always direct users to the most recent version of the document.

3 Overview

Standard number	DAPB0108
Title	Automatic Identification and Data Capture (AIDC)
Release	Amd 1/2022
Type	Information Standard
Definition	<p>DAPB0108 is an information standard developed by GS1 UK and endorsed by NHS via NHS England and NHS Improvement sponsor and NHS Digital SRO.</p> <p>GS1 UK have worked with NHS Digital to update the above NHS standard that applies to NHS settings in England where Automatic Identification and Data Capture (AIDC) technologies (i.e. barcodes and RFID tags) are used as enablers to improve patient safety, ensure greater clinical effectiveness and drive operational efficiencies.</p> <p>As the previous version, ISB 0108, was last published in 2011, there are a number of GS1 Standards and NHS changes which require alignment. This release includes the following updates:</p> <ul style="list-style-type: none"> • Serialised Global Trade Item Number (SGTIN) which enables the identification of a specific instance of an item, providing additional granularity for traceability purposes. • Service Relation Instance Number (SRIN) which enables the identification of specific episodes of care and is an extension to the Global Service Relation Number (GSRN), defined for use by DCB1077: AIDC for Patient Identification • Global Model Number (GMN) to address regulatory requirements² for medical devices used in the UK, including in vitro diagnostic medical devices • Radio Frequency Identification (RFID) added to GS1 Data Carriers • Updated information on GS1 Data Carriers, barcode production, barcode quality and compliance (excluding RFID) • Updated diagrams and references to GS1 Standards such as the GS1 Healthcare Global Trade Item Number (GTIN) Allocation Standard • All references to supporting links and guidance, glossary, appendices, governing bodies, and contract dates, updated • Sections updated and re-formatted to align to revised DSAS publication guidance for consistency
Background	<p>GS1 UK is one of 115 member organisations, with over 56,000 members across various sectors including NHS organisations, striving towards the adoption of GS1 Standards. With multi-year partnership agreements established with healthcare governing bodies across each of the UK nations, both regulatory and business needs throughout NHS Trusts in England and the healthcare sector, can be addressed through the adoption of GS1 Standards across various health systems.</p> <p>GS1 Standards for AIDC technologies and applications are developed and maintained collaboratively by industry users worldwide, enabling organisations to use a common language to identify, capture and share information for traceability and interoperability. The best known of these standards is the barcode, a symbol printed on products that can be scanned electronically at point of sale.</p> <p>The introduction of the Medicines and Medical Devices Act (MMDA) in February 2021 has enabled the UK to have more authority over how it regulates medicines and medical</p>

² UK government guidance on regulating medical devices in the UK can be found at <https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk#legislation-that-applies-in-great-britain>

	<p>devices by encouraging the use of existing industry standards such as GS1 Standards. This includes the Medical Device Register (MDR) developed by the Medicines and Healthcare products Regulatory Agency (MHRA), which ensures that every medical device used in the UK is certified and registered in a central registry with a unique identifier and key information, in a standardised format.</p>
Benefits	<p>The adoption of GS1 Standards, enables improved data quality allowing information to be exchanged seamlessly between systems and organisations to support the delivery of greater patient safety improvements, enhance clinical effectiveness, and reduce unwarranted clinical variation. By unlocking improved data accuracy for Trust records, increased operational efficiencies can be achieved, reducing administrative burdens with tasks such as inventory and asset management or patient level costings, and releasing more time back to patient care³.</p> <p>This has been previously demonstrated by the NHS Trust demonstrator sites through the Scan4Safety (S4S) programme⁴, where six trusts were tasked with implementing GS1 standards for the unique identification of every person, every product and every place within healthcare. The programme found that through the use of GS1 standards over a two-year period across the six trusts:</p> <ul style="list-style-type: none"> • 140,000 hours of clinical time released to care • Almost £5m of recurrent inventory savings • £9m of non-recurrent inventory reductions <p>This provided a positive impact in areas for Patient Safety, Theatres, Pharmacy, Finance and Inventory departments.</p> <p>Furthermore, the use of GS1 Standards supports initiatives such as the Medical Device Information System (MDIS), which is currently being developed by NHS Digital to enable efficient track and trace of medical devices to patients as well as details of the place where the procedure occurred, and which clinicians were involved. Additionally, the MDIS directly addresses the recommendations outlined by Baroness Cumberlege's Independent Medicines and Medical Devices Safety Review "First Do No Harm" around the creation of a central patient-identifiable database to collect key details of the implantation of all devices at the time of the operation which can then be linked to specifically created registers to research and audit the outcomes both in terms of the device safety and patient reported outcomes measures.</p>
Scope	<p>DAPB0108 is a technology enabling standard aimed at individual NHS Trusts in England, which provides the specification for achieving accurate Automatic Identification and Data Capture (AIDC) using GS1 Standards. It SHOULD be used as a reference tool by the NHS when procuring, implementing, and using AIDC technologies, e.g., barcode encoding software, scanners and printers. It includes an overview of:</p> <ul style="list-style-type: none"> • GS1 Identification Keys, including data structure and supported data attributes where all NHS Trusts have access to today via their membership with GS1UK • GS1 Data Carriers (i.e., barcodes and RFID tags) • How to produce compliant GS1 barcodes and RFID tags, using GS1 Application Standards and Symbol Specifications • How to ensure optimal barcode quality and compliance to GS1 Standards, including barcode and RFID validation and verification requirements <p>It is the primary standard in a series of AIDC standards for the NHS in England. As AIDC standards are approved by the Data Alliance Partnership Board (DAPB), they will be published on the NHS Digital Standards and Collections webpage.</p>

³ GS1 UKs Healthcare Case Studies with NHS Trusts and providers can be found at <https://healthcare.gs1uk.org/cases/>

⁴ Following completion of the S4S programme, a report on the accumulated data and insights has been published at <https://healthcare.gs1uk.org/scan4safety/>

	<p>Out of scope for this Information Standard are:</p> <ul style="list-style-type: none">• DCB1077 AIDC for Patient Identification.• Barcoding and identification of blood and biological medical product of human origin (MHRO)• Any business processes that adoption of this standard will enable e.g., scanning of barcodes and system design etc. <p>Impacted organisations and staff include those involved in the procurement, deployment and use of AIDC systems which use GS1 Standards across NHS England, as well as those associated with the provision of care to the patient. These MAY include:</p> <ul style="list-style-type: none">• IT and informatics personnel• Finance and procurement• Departmental directors and managers• Project managers• Healthcare professionals• Administration staff• Estates and facilities management
--	---

4 Concept of Use

4.1 GS1 Standards

GS1 Standards allow for use within Automatic Identification and Data Capture (AIDC) applications and technologies, enabling the use of unambiguous identification keys to identify goods, services, assets, locations, etc. worldwide. Across healthcare, GS1 keys enable, where used, the identification of every person, product, and place across the patient pathway.

These keys can be represented in data carriers, such as barcodes or EPC/RFID tags, to enable automatic data capture when scanned or read. They can also be used in electronic communications, improving speed and accuracy when sharing product data, transactional data, and event data.

4.2 GS1 Standards Management Process (GSMP)

GS1 develop global standards in collaboration with industry experts and business teams, through the [GS1 Standards Management Process \(GSMP\)](#). The users of GS1 Standards drive changes by working in specialist GSMP work groups with fellow industry participants and GS1 member organisations from around the globe.

The GS1 Standards development teams and subject matter experts guide regular updates of new and existing GS1 Standards through a document development life cycle, ensuring all rules and changes published are harmonised and agreed to by participants of the working groups. The GSMP ensures the creation and adoption of new standards aligns with industry needs and can be achieved with rapid consensus smoothly and fairly.

4.3 GS1 and ISO/IEC Standards

Working with GS1 Standards means working with ISO/IEC compliant standards, with the added value of services, training, and implementation support. GS1 adopts ISO/IEC standards where they meet the needs of its members and puts forward standards it has developed for adoption by ISO/IEC.

4.4 GS1 General Specifications

The [GS1 General Specifications](#) defines the rules for use of GS1 Standards within AIDC applications and technologies. Every organisation using GS1 Standards is expected to conform fully to the GS1 General Specifications. DAPB0108 provides a selection of healthcare relevant content adapted from the GS1 General Specifications with details of section headings and numbers⁵ provided for further information. These GS1 General Specifications sections **MUST** be referenced to meet full compliance to GS1 Standards and DAPB0108.

⁵ Please refer to section headings where possible, as section numbers may change when the GS1 General Specifications are republished annually.

4.5 GS1 Membership

In order to apply GS1 keys for the identification of every person, product and place across the patient pathway, every organisation must be a member of a GS1 Member Organisation. With a membership, an organisation is assigned a company prefix and a number range that is globally unique. All NHS Trusts today are members of GS1.

This ensures globally unique, accurate, standards-based numbers are used to identify, capture and share information accurately within the NHS.

5 Requirements

This document outlines requirements using MUST (or MUST NOT), SHOULD (or SHOULD NOT) and MAY (or MAY NOT) statements as defined by [RFC-2119](#).

5.1 Information Specification

#	Requirements
General	
1.	DABP0108 SHOULD be used as a reference tool by the NHS when procuring, implementing, and using AIDC technologies such as barcode encoding software, scanners, and printers.
2.	GS1 General Specifications section headings and numbers have been provided throughout this document and MUST be referenced to meet compliance to each relevant section of DAPB0108.
3.	DAPB0108 MUST NOT be used for the management and tracking of blood products or other biological medical product of human origin (MHRO) as this is addressed by the ICCBBA technical standard ISBT-128.
4.	Users MUST perform a clinical safety assessment when using this standard in a clinical setting, in accordance with the NHS Digital information standards DCB0160: Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems, and DCB0129: Clinical Risk Management: its Application in the Manufacture of Health IT Systems, to identify and acceptably manage clinical safety risk associated with solution / system design, context of use and human factors.
GS1 Identification (prefix management and data requirements)	
5.	All NHS trusts who are already members SHOULD manage their prefixes and allocate GTINs and Global Location Numbers (GLNs) through the dedicated GS1 UK member portal, MyNumberbank (please see Appendix 1 for more info on MyNumberbank).
6.	A GCP is unique to the member whom it is licenced to, therefore Trusts MUST notify GS1 UK of any legal status changes as a result of an acquisition, merger, partial purchase, split or “spin-off”, within one year of that change to facilitate a smooth transition.
7.	GS1 Identification Keys and attributes MUST adhere to the data formats shown in Section 7, in line with the “Application Standards” and “Application Identifier Definition” sections referenced in the GS1 General Specifications.
8.	If using 96-bit RFID tags, GS1 Identification Keys and attributes MUST also adhere to the data formats referenced in the “EPC Binary Coding Schemes” section of the GS1 EPC Tag Data Standard (TDS).
9.	All data MUST be encoded with the GS1 Subset of ISO/IEC 646 (equivalent to ASCII table 256), as per the GS1 AI encodable character set 82 table, shown in Appendix 2. Space characters are invalid and MUST NOT be encoded.
10.	GS1 Application Identifiers (AI) MUST be used when encoding GS1 Identification Keys and any supplementary attribute data to GS1 Data Carriers, as outlined in Section 7, in line with the “Application Identifier Definition” sections referenced in the GS1 General Specifications.
11.	GS1 Identification Keys MUST adhere to the usage and allocation rules outlined in Section 7, in line with the “Application Standards” sections referenced in the GS1 General Specifications, which also include the GS1 Healthcare GTIN Allocation Rules Standard and GLN Allocation Rules Standard.
12.	All data MUST adhere to the complete invalid pairs and mandatory pairs of element strings tables explained in Section 7, in line with the “Data Relationships” section referenced in the GS1 General Specifications.
GS1 Data Carriers (barcode production and management)	

13.	GS1 barcodes MUST include all technical characteristics and requirements such as start sequence characters and quiet zones, as outlined in Section 8, in line with the “Data Carriers” sections referenced in the GS1 General Specifications (and the GS1 DataMatrix Guidelines if the GS1 DataMatrix is being adopted).
14.	If RFID is to be adopted, the GS1 EPC Tag Data Standards (TDS) MUST be referenced to meet compliance to DAPB0108. The full suite of GS1 Standards which complement the TDS such as the EPC/RFID Air Interface protocols SHOULD be referenced at GS1 RFID Standards homepage .
15.	When structuring data in concatenated barcodes, AIs with fixed length data content SHOULD be placed at the beginning and AIs with variable lengths SHOULD be placed at the end.
16.	If more than one variable length or non-predefined length AI is placed in a single barcode, a Function 1 (FNC1) separator character MUST be used if followed by another element string. No FNC1 is needed at the end of the last data item in a string.
17.	Symbol Placement MUST adhere to the guidance outlined in Section 8, in line with the complete set of application specific rules, such as for General Distribution or Logistics Labels, shown in the “Symbol Placement Guidelines” section referenced in the GS1 General Specifications.
18.	Multiple Barcode Management MUST adhere to the guidance outlined in Section 8, in line with the complete set of application specific rules, including the rules applicable to regulated healthcare items that are required to be scanned at both retail pharmacy and non-retail pharmacy/bedside, shown in the “Multiple Barcode Management Practices” section referenced in the GS1 General Specifications.
19.	The use of Human Readable Interpretation (HRI) MUST adhere to the guidance outlined in Section 8, in line with the complete set of application specific rules including guidance for use in healthcare, shown in the “Human Readable Interpretation (HRI) rules” section referenced in the GS1 General Specifications. Exceptions MAY occur only when local regulatory or legal requirements mandate otherwise.
20.	When indicating an element string in the non-HRI text section of a barcode label, the data titles outlined for each GS1 Identification Key and attribute in Section 7 and referenced in the “GS1 Application Identifier Definitions” section of the GS1 General Specifications SHOULD be used.
21.	To choose the correct GS1 Data Carrier for the required application, the “Application Standards” section of the GS1 General Specifications MUST be referenced.
22.	To ensure GS1 Data Carriers are able to function optimally and consistently in the required scan environment, the size and minimum quality specifications defined by the “GS1 Symbol Specifications Tables” section of the GS1 General Specifications MUST be adhered to.
Data Carrier Quality and Compliance (validation and verification processes)	
23.	The accurate printing of barcodes is fundamental to successful scanning. Therefore, barcode production MUST include robust validation and verification practices as a standard part of the process.
24.	Barcode validation is carried out on a soft copy barcode sample, which MAY be a photo, scan, or image file of the barcode label, wristband sample, or simply the barcode itself. Whatever the file type, soft copy samples MUST be a high-quality image, without blurring, pixilation, or any type of distortion. All barcode samples SHOULD pass validation before a physical sample is produced and sent in for verification.
25.	Barcode verification MUST be carried out on a physical sample of the barcode label or wristband sample, in its final configuration. If any part of the barcode production process is altered, such as a change to the print technique or equipment, material/substrate type, or any re-design or re-configuration of the barcode label, a new physical sample SHOULD be re-submitted for verification.
26.	If an RFID tag is also barcoded, the barcode validation and verification process MUST be followed, meaning a soft copy sample of the barcode SHOULD be submitted for validation first, ahead of sending any physical sample.

5.2 Conformance Criteria

For every MUST/MUST NOT requirement, an equivalent Conformance Criterion is noted in the table below.

#	Conformance Criteria
General	
1.	The GS1 General Specifications section headings and numbers have been referenced to meet compliance to DAPB0108.
2.	DAPB0108 have not been used to manage and track blood products or other biological medical products of human origin (MHRO), which is addressed by the ICCBBA technical standard ISBT-128.
3.	When using this standard in a clinical setting, users have performed a clinical safety assessment in accordance with the NHS Digital information standards DCB0160: Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems, and DCB0129: Clinical Risk Management: its Application in the Manufacture of Health IT Systems.
GS1 Identification (prefix management and data requirements)	
4.	In the event of any legal status changes as a result of an acquisition, merger, partial purchase, split or "spin-off", the Trust has notified GS1 UK within one year of that change.
5.	GS1 Identification Keys and attributes adhere to the data formats shown in Section 7, in line with the "Application Standards" and "Application Identifier Definition" sections referenced in the GS1 General Specifications.
6.	If using 96-bit RFID tags, GS1 Identification Keys and attributes also adhere to the data formats referenced in the "EPC Binary Coding Schemes" section of the GS1 EPC Tag Data Standard (TDS).
7.	All data is encoded with the GS1 Subset of ISO/IEC 646 (equivalent to ASCII table 256), as per the GS1 AI encodable character set 82 table, shown in Appendix 2. Space characters are not encoded.
8.	GS1 Application Identifiers (AI) are used when encoding GS1 Identification Keys and any supplementary attribute data to GS1 Data Carriers, as outlined in Section 7, in line with the "Application Identifier Definition" sections referenced in the GS1 General Specifications.
9.	GS1 Identification Keys adhere to the usage and allocation rules outlined in Section 7, in line with the "Application Standards" sections referenced in the GS1 General Specifications, which also include the GS1 Healthcare GTIN Allocation Rules Standard and GLN Allocation Rules Standard.
10.	All data adheres to the complete invalid pairs and mandatory pairs of element strings tables explained in Section 7, in line with the "Data Relationships" section referenced in the GS1 General Specifications.
GS1 Data Carriers (barcode production and management)	
11.	GS1 barcodes include all technical characteristics and requirements such as start sequence characters and quiet zones, as outlined in Section 10, in line with the "Data Carriers" sections referenced in the GS1 General Specifications (and the GS1 DataMatrix Guidelines if the GS1 DataMatrix is being adopted).
12.	If RFID is to be adopted, the GS1 EPC Tag Data Standards (TDS) is referenced to meet compliance to DAPB0108.
13.	If more than one variable length or non-predefined length AI is placed in a single barcode, a Function 1 (FNC1) separator character is used if followed by another element string.
14.	Symbol Placement adheres to the guidance outlined in Section 8, in line with the complete set of application specific rules, such as for General Distribution or Logistics Labels, as shown in the "Symbol Placement Guidelines" section referenced in the GS1 General Specifications.

15.	The use of Multiple Barcodes adheres to the guidance outlined in Section 8, in line with the rules applicable to regulated healthcare items that are required to be scanned at both retail pharmacy and non-retail pharmacy/bedside, shown in the "Multiple Barcode Management Practices" section referenced in the GS1 General Specifications.
16.	The use of Human Readable Interpretation (HRI) adheres to the guidance outlined in Section 8, in line with the complete set of application specific rules including guidance for use in healthcare, shown in the "Human Readable Interpretation (HRI) rules" section referenced in the GS1 General Specifications.
17.	To choose the correct GS1 Data Carrier for the required application, "Application Standards" in section 2 of the GS1 General Specifications is referenced.
18.	To ensure GS1 Data Carriers are able to function optimally and consistently in the required scan environment, the size and minimum quality specifications defined by "GS1 Symbol Specifications Tables" in section 5 of the GS1 General Specifications are adhered to.
Data Carrier Quality and Compliance (validation and verification processes)	
19.	Barcode production includes robust validation and verification practices as a standard part of the process, to ensure barcodes are printed accurately and scan successfully.
20.	Soft copy samples submitted for barcode validation are a high-quality image, without blurring, pixilation, or any type of distortion.
21.	Barcode verification is be carried out on a physical sample of the barcode label or wristband sample, in its final configuration.
22.	If an RFID tag is also barcoded, the barcode validation and verification process is followed.

6 Legal Position of GS1

GS1 provides voluntary, royalty-free standards which enable users to meet local, national, and global regulatory compliance through the use of interoperable data and data carriers.

However, neither GS1, its member organisations nor their staff have real or apparent authority to speak for the regulatory authorities or grant exemptions. GS1 offers advisory services focused on GS1 Standards, after supplier's staff, including its internal regulatory experts, have determined the correct path to compliance.

GS1 is a voluntary organisation, and its members must continue to determine their own course of action. GS1 provides recommendations only. GS1 Global Office, GS1 member organisations (including GS1UK) and GS1 staff assume no liability for members actions taken upon its advice.

Local, national, and global regulations will take precedence over any requirements provided by GS1 Standards.

7 GS1 Identification Standards

To identify something clearly and consistently, a globally unique and unambiguous number is needed. GS1 Standards defines the requirements to create these numbers, known as GS1 Identification Keys.

This section provides an overview of GS1 Standards for identification, explaining how to obtain and use a GS1 Company Prefix (GCP) for the creation of GS1 Identification Keys.

The required data structure and purpose of each GS1 Identification Key, is explained below alongside potential healthcare uses. Also included is guidance on the use of GS1 Application Identifiers (AI) which enable the correct interpretation of each GS1 Identification Key as well as any associated supplementary data required for further granularity.

7.1 GS1 Company Prefix (GCP)

A GS1 Company Prefix (GCP) is a unique string of four to twelve digits licenced by the GS1 member organisation (MO) of the region and is used to create and allocate GS1 Identification Keys, typically in batches of 1,000, 10,000, or 100,000 numbers.

GS1 UK is the MO for members across the 4 UK nations, England, Scotland, Northern Ireland and Wales. As part of the GS1 UK membership contract with NHS Digital (next renewal March 2024), all NHS Trusts in England have access to a GCP, enabling any hospital or organisation under their remit, to begin using and allocating GS1 Identification Keys.

The GCP is unique to the member whom it is licenced to and requires the member to be responsible for ensuring the keys created from that prefix are allocated correctly and are globally unique. All members SHOULD manage their prefixes through the dedicated GS1 UK member portal, My Numberbank (further information may be found in [Appendix 1](#)).

Additional guidelines apply when a Trust changes legal status as a result of an acquisition, merger, partial purchase, split or “spin-off”. Therefore, Trusts MUST notify GS1 UK of any legal status changes within one year of that change to facilitate a smooth transition.

For further information on NHS Trust membership, how to obtain a GCP, request additional GCP for more numbers or advise of changes to legal status, please email healthcare@gs1uk.org.

7.2 GS1 Identification Keys

GS1 Identification Keys are globally unique and unambiguous numbers which identify different types of objects or entities. Depending on what needs to be identified, for example, whether it's a person, product or place, there is a specific GS1 Identification Key to use.

Each GS1 Identification Key is associated with a concept in the real world. The keys can then be used on the physical item, in an electronic record or file, in a database, in an electronic message, or in any other data context. Thus, a GS1 Identification Key is used to link database information to the physical entity unambiguously.

The following table outlines some intended areas of application, including examples across the healthcare sector and the corresponding GS1 Identification Key, with further information provided in the following sub-sections.

Figure 1: Table of GS1 Identification key uses, examples and key types

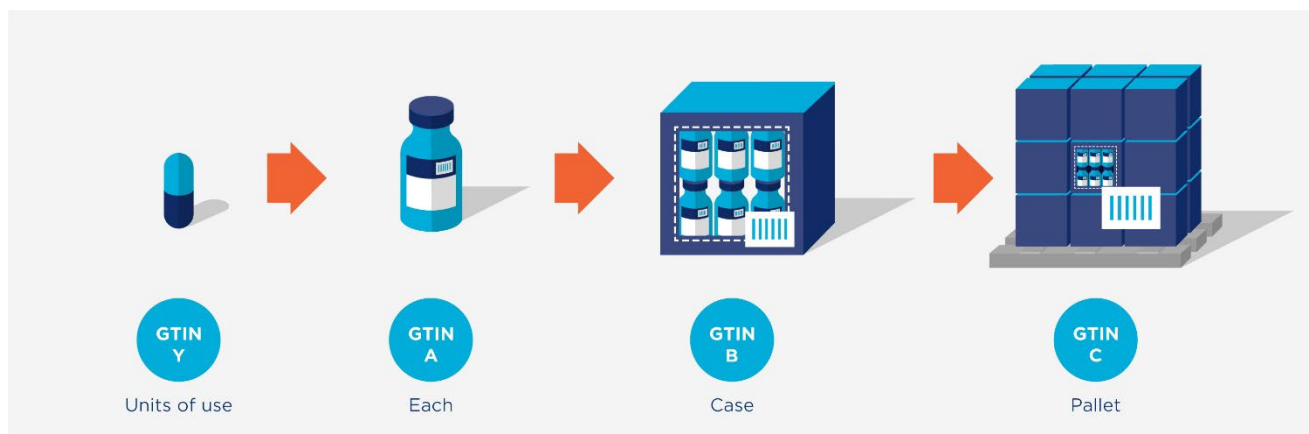
What needs to be identified	Healthcare application example	GS1 Identification Key required
Products or services that are traded/transacted	NHS manufactured and re-packaged medicines; services such as a medical procedure or sterilisation event.	Global Trade Item Number (GTIN) See section 7.2.1
Service relationships between providers and recipients	Service providers such as caregivers, facilities, or administration staff; service recipients such as patients, clients, or members.	Global Service Relation Number (GSRN) See section 7.2.2
Locations and organisations (i.e., legal, or departmental entities)	Physical locations such as individual hospital or care sites, suppliers, or specific wards and stock locations; organisational entities or parties such as NHS Trusts or an accounts payable department.	Global Location Number (GLN) See section 7.2.3
Document types	Case notes; patient letters; instructional or promotional leaflets.	Global Document Type Identifier (GDTI) See section 7.2.4
Logistics units	Pallets, containers, roll cages.	Serial Shipping Container Code (SSCC) See section 7.2.5
Assets	Surgical instruments, medical devices, or equipment e.g., IV pumps, surgical kit trays	Global Individual Asset Identifier (GIAI) See section 7.2.6
Returnable assets used for transportation	Pallet bases, crates, totes, trolleys, cannisters.	Global Returnable Asset Identifier (GRAI) See section 7.2.7
Model type	Identifies the model or family type of medical devices for regulatory databases.	Global Model Number (GMN) See section 7.2.8

7.2.1 GTIN: Global Trade Item Number

The GTIN is a GS1 Identification Key used to identify products or services that could be priced, ordered, or invoiced at any point in any supply chain. As a unique and unambiguous identifier for the product or service, the GTIN can be used to retrieve pre-defined information about the item from a database e.g., a price can be looked up for check-out at point-of-sale.

This means that the healthcare sector can identify pharmaceuticals, instruments, and medical devices for example, with a GTIN which can then be used throughout inventory-management and supply-chain processes, including product recalls if required. Each different level of packaging MUST have its own GTIN, including single units of use for some types of items.

Figure 2: Example GTIN hierarchy for a pharmaceutical item



For regulated healthcare products such as medical devices and in-vitro diagnostic devices, the GTIN can fulfil the role of the Unique Device Identification-Device Identifier (UDI-DI) for regulatory purposes. To comply with regulations for medical devices and in vitro diagnostic medical devices, the GTIN is used for device certification and registration, along with the Global Model Number (GMN), which is explained in [section 7.2.8](#).

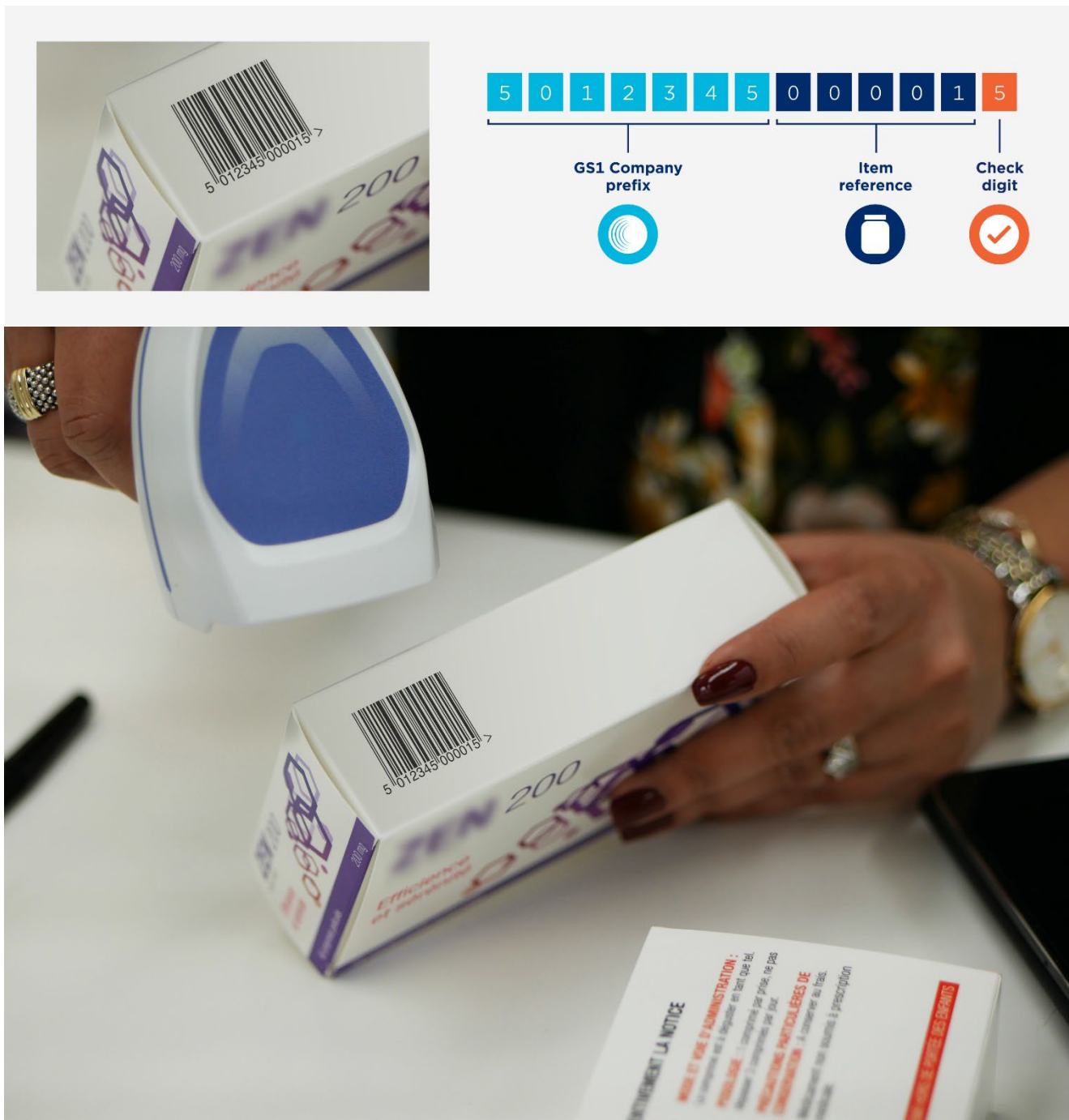
GTINs require the application identifier, AI, (01) and can be either 8, 12, 13 or 14 digits in length, including a check digit. See [Appendix 3](#) for more information on check digits. The GTIN MUST adhere to the format shown below.

Figure 3: Format of the GTIN element string

	GS1 Application Identifier	Global Trade Item Number (GTIN)													
		GS1-8 Prefix or GS1 Company Prefix							Item reference						Check digit
(GTIN-8)	0 1	0	0	0	0	0	0	N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	
(GTIN-12)	0 1	0	0	N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂
(GTIN-13)	0 1	0	N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂	N ₁₃
(GTIN-14)	0 1	N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂	N ₁₃	N ₁₄

When indicating this element string in the non-HRI text section of a barcode label, the following data title SHOULD be used: **GTIN**

Figure 4: An example of a GTIN-13 encoded to an EAN-13 barcode (including example of data structure), typically used on pharmaceutical products sold or dispensed over the counter (OTC), as well as within robotic dispensing systems.



Applications where a GTIN is allocated by NHS Trusts:

- Identification of surgical instruments, including direct part marking of medical devices (non-retail trade items)
- Healthcare primary packaging (non-retail trade items), such as procedure kits or individual instruments for sterilisation or decontamination services, further information MAY be found in the [GS1 UK Surgical Instrument Traceability Guidance](#)
- Healthcare secondary packaging (regulated healthcare retail consumer trade item)
- Clinical trials (GTIN + protocol ID), further information MAY be found in the [GS1 Identification of Investigational Products in Clinical Trials Application Standard](#)

Application rules and management practices:

For GS1 UK members, GTINs SHOULD be allocated and managed through My Numberbank (please see [Appendix 1](#) for more info on MyNumberbank). The range of numbers available is dependent on the length of the GCP which is licenced. For example, a 7-digit prefix will provide 100,000 GTIN-13s; an 8-digit prefix will provide 10,000 GTIN-13s.

Within healthcare, the details on when to change a GTIN, including the rules around GTIN non-reuse, are defined by the [GS1 Healthcare GTIN Allocation Rules Standard](#). These rules MUST be complied with, to ensure a globally harmonised framework for the implementation of GS1 Standards across NHS Trusts in England, in order to improve supply chain efficiency and ensure patient safety. However regulatory requirements always take precedence.

For further information on GS1 Standards for Trade Items, including Medical Devices, the “Application Standards” in section 2 of the GS1 General Specifications MUST be referred to.

7.2.1.1 SGTIN: Serialised Global Trade Item Number

A Serialised GTIN (SGTIN) is a GTIN and a Serial Number, which is used to identify a specific instance of a trade item, providing an extra level of granularity for traceability purposes.

A Serial Number MUST be unique to each GTIN and is always to be understood as an attribute of a GTIN. Only the combination of both guarantees uniqueness, so a serial number MUST always be read and processed with the GTIN.

In cases where the manufacturer has not marked an instrument and a Trust wishes to, Trusts MAY use their own SGTIN. If an instrument has been marked with a manufacturer SGTIN, this SHOULD continue to be used by the Trust (and cross-referenced to their own identifiers, if required). For further information on surgical instrument traceability, including sterilisation services, across NHS Trusts, the [GS1 UK Surgical Instrument Traceability Guidelines](#) SHOULD be referred to.

The Serial Number uses AI (21) and is variable length, up to a maximum of 20 alphanumeric characters which MAY include all characters contained in [Appendix 2](#). The Serial Number MUST adhere to the format shown below.

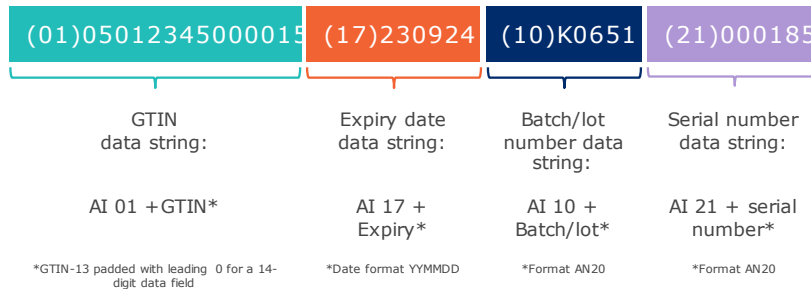
Figure 5: Format of the Serial Number element string

GS1 Application Identifier	Serial number
2 1	X ₁ ————— variable length ————— > X ₂₀

When indicating this element string in the non-HRI text section of a barcode label, the following data title SHOULD be used: **SERIAL**

Application rules and management practices:

Figure 6: An example of a GTIN-13 encoded with Serial Number and other attribute data in a GS1 DataMatrix barcode, typically used on pharmaceutical products in the UK to comply with the [Falsified Medicines Directive 2011/62/EU \(FMD\)](#).



Whilst Serial Number (21) is optional, when used, it **MUST** always be processed together with a GTIN (01) as it is an attribute of a trade item. See [section 7.4](#) on Data Relationships for further information.

A serial number is assigned to an entity for its lifetime.

The format of the serial number is at the discretion of the party responsible but **MUST** adhere to the structure outlined above. For further information, “GS1 Application Identifier Definitions” in section 3 of the GS1 General Specifications **MUST** be referred to.

If the SGTIN is to be encoded to a 96-bit RFID tag, the data format **MUST** also adhere to the “EPC Binary Coding Schemes” outlined in the GS1 EPC Tag Data Standard (TDS).

7.2.2 GSRN: Global Service Relation Number

The GSRN is a GS1 Identification Key used to identify a relationship between a service provider and a service recipient. In simple terms, a company or business will issue a GSRN to a customer to identify their relationship. This could be a club membership, a member of a loyalty scheme or to identify a patient using NHS services.

The GSRN only identifies a business or individual in the context of the service relation, and in this way limits privacy concerns.

Across the NHS in England, patients are identified with a GSRN for a service recipient. The GSRN is assigned by the service provider, which in the case of the NHS Digital information standard DCB1077: AIDC for Patient Identification, is NHS Digital, as the service provider of the NHS number.

The GSRN for a service provider is used to identify care givers and other hospital staff.

The GSRN uses AI (8017) for a provider and (8018) for a recipient; and is a fixed length of 18 numeric characters, including a check digit. See [Appendix 3](#) for more information on check digits. The GSRN MUST adhere to the format shown below.

Figure 7: Format of the GSRN element string

GS1 Application Identifier	Global Service Relation Number (GSRN) - PROVIDER																	Check digit
	GS1 Company Prefix								Service reference									
8 0 1 7	N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂	N ₁₃	N ₁₄	N ₁₅	N ₁₆	N ₁₇	N ₁₈

GS1 Application Identifier	Global Service Relation Number (GSRN) - RECIPIENT																	Check digit
	GS1 Company Prefix								Service reference									
8 0 1 8	N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂	N ₁₃	N ₁₄	N ₁₅	N ₁₆	N ₁₇	N ₁₈

When indicating this element string in the non-HRI text section of a barcode label, the following data title SHOULD be used: **GSRN – PROVIDER / GSRN – RECIPIENT**

Applications where GSRN is allocated by NHS Trusts:

- Primary identification key for a patient, used within the patient identification data set for identity bands, defined by NHS information standard DCB1077
- Primary identification key for caregivers and other hospital staff such as facilities, trade, or temporary staff.

Figure 8: An example of a patient wristband



Application rules and management practices:

AI (8017) and AI (8018) MUST NOT be used in combination. See [section 7.4](#) on Data Relationships for further information.

The exact method used to allocate the Global Service Relation Number (GSRN) is left to the discretion of the issuing organisation. A GSRN with either AI (8018) or AI (8017) are mutually exclusive, that is, a GSRN can only be assigned to a single role, recipient, or provider, but not both.

For further information on GS1 Standards for Service Relationships, the “Application Standards” in section 2 of the GS1 General Specifications MUST be referred to.

7.2.2.1 SRIN: Service Relation Instance Number

The SRIN is an optional extension to the GSRN that identifies a specific service instance, in relation to a service provider or recipient.

For a service recipient, such as a patient, the SRIN identifies a specific encounter as defined by NHS Digital information standard DCB1077: AIDC for Patient Identification. For example, if the treatment plan requires different instances of care, such as for chemotherapies, and when a record needs to be captured for each instance, the SRIN linked to the GSRN MAY be used. Therefore, if the subject of care identification needs to, optionally, be made more granular with a sequence indicator corresponding to each encounter during the episode of care, the SRIN MAY be used.

For a service provider, the SRIN linked to the GSRN MAY be used to identify a staff badge. If the badge is decommissioned or replaced, a new SRIN linked to the existing GSRN will be assigned, providing a means for the organisation issuing badges to distinguish between badges with identical GSRNs.

The SRIN uses AI (8018) and is a variable length, up to a maximum of 10 numeric characters. The SRIN MUST adhere to the format shown below.

Figure 9: Format of the SRIN element string

GS1 Application Identifier	Service Relation Instance Number
8 0 1 9	N ₁ —————variable length—————> N ₁₀

When indicating this element string in the non-HRI text section of a barcode label, the following data title SHOULD be used: **SRIN**

Application rules and management practices:

Whilst the SRIN (8019) is optional, when used, it MUST be processed together with a GSRN (8017) or (8018) as it is an attribute of a GSRN. See [section 7.4](#) on Data Relationships for further information.

The content of the SRIN is at the discretion of the organisation offering the service, in order to uniquely identify each service relation instance and MUST adhere to the structure outlined above. For further information, “GS1 Application Identifier Definitions” in section 3 of the GS1 General Specifications MUST be referred to.

7.2.3 GLN: Global Location Number

The GLN is a GS1 Identification Key used to identify any type of location or party used in business processes. This could mean a physical location like a warehouse, store, or factory or somewhere more granular, like a delivery bay or even a shelf. In addition, GLNs are used to identify digital locations such as an Enterprise Resource Planning (ERP) system or Warehouse Management System (WMS), as well as functions and organisations such the buying or accounts department as well as entire companies or operating divisions.

In healthcare, GLNs are used not only for supply chain and departmental locations but also to identify, for example, wards, nurses' stations, and bed bays. GLNs are often used in communications, especially electronic communications, such as orders or advance shipping notes, to identify relevant locations like where goods should be delivered and where the invoice should be sent.

The GLN is a fixed length of 13 digits, including a check digit and is shown in figure 10 with AI (414) for a physical location. See [Appendix 3](#) for more information on check digits. The GLN MUST adhere to the format shown below in figure 10 and figure 11.

Figure 10: Format of the GLN element string

GS1 Application Identifier	GS1 Company Prefix	Location reference	Check digit
4 1 4	N ₁ N ₂ N ₃ N ₄ N ₅ N ₆ N ₇ N ₈ N ₉ N ₁₀ N ₁₁ N ₁₂		N ₁₃

Figure 11: Application Identifiers (AI) to define the specification of a GLN

GS1 Application Identifier	Application Identifier Name	Data Format	Data Title
410	Deliver to GLN	n3 + n13	SHIP TO LOC
411	Invoice to GLN	n3 + n13	BILL TO
412	Purchased from GLN	n3 + n13	PURCHASE FROM
413	Deliver for/forward to GLN	n3 + n13	SHIP FOR LOC
414	Identification of physical FROM location	n3 + n13	LOC. NO
415	GLN of the invoicing party	n3 + n13	PAY TO

When indicating the GLN element string in the non-HRI text section of a barcode label, the data titles shown in figure 11 SHOULD be used.

Figure 12: An example of a GLN for a physical location encoded to a GS1-128 barcode



Figure 13: An example of a GLN for a physical location encoded to a GS1-128 barcode in practice



Applications where GLN is allocated by NHS Trusts:

- Identification of physical locations such as wards, theatres, storerooms, or delivery points
- Identification of a digital (non-physical) location such as an email address
- Identification of organisations or legal entity such as a local hospital within a Trust
- Identification of functions or departments such as accounts or payroll
- Further information MAY be found in the [GS1 Healthcare GLN Implementation Guideline](#)

Application rules and management practices:

For GS1 UK members, GLNs SHOULD be allocated and managed through My Numberbank (please see [Appendix 1](#) for more info on MyNumberbank). The range of numbers available is dependent on the length of the GCP which is licenced. For example, a 7-digit prefix will provide 100,000 numbers. An 8-digit prefix will provide 10,000 numbers.

The details on when to change a GLN, including the rules around GLN non-reuse, are defined by the [GLN Allocation Rules Standard](#). These rules MUST be complied with, to ensure a globally harmonised framework for the implementation of GS1 Standards across NHS Trusts in England, in order to improve supply chain efficiency and ensure patient safety.

All key healthcare stakeholders involved in the manufacture, distribution, supply, purchase and use of healthcare products and equipment SHOULD also use [LocationManager](#) to share GLNs for organisations and their significant locations and search for other GLNs across the NHS (please see [Appendix 7](#) for more info on LocationManager).

For further information on GS1 Standards for Locations and Parties, the “Application Standards” in section 2 of the GS1 General Specifications MUST be referred to.

7.2.3.1 GLN Extensions

GLNs for physical locations MAY also include an optional extension component to identify sub-locations (e.g., beds/bays) within a location identified with a GLN (e.g., wards) or to distinguish unique locations (e.g., storage slots, door locations, bin storage, shelves, peg holes, rack, cabinet, computer/communication bays, etc.).

A company MAY also choose to assign a unique GLN, without an extension component, as a way to identify these locations, however more numbers will be used up from the licensed allocation in this way.

The GLN extension component uses AI (254) and is variable length, up to a maximum of 20 alphanumeric characters which MAY include all characters contained in [Appendix 2](#). The GLN extension component MUST adhere to the format shown below.

Figure 14: Format of the GLN extension element string

GS1 Application Identifier	GLN extension component
2 5 4	X ₁ ————— variable length —————> X ₂₀

When indicating this element string in the non-HRI text section of a barcode label, the following data title SHOULD be used: **GLN EXTENSION COMPONENT**

Application rules and management practices:

Whilst the GLN Extension Component (254) is optional, when used, it MUST be processed together with a GLN (414) as it is an attribute of a physical location. See [section 7.4](#) on Data Relationships for further information.

The party who defined the location determines the extension component. Once determined, it is unchanged for the life of the associated GLN. The format of the GLN extension is at the discretion of the party responsible, but it MUST adhere to the structure outlined above.

For further information, “GS1 Application Identifier Definitions” in section 3 of the GS1 General Specifications MUST be referred to.

If the GLN extension component + GLN is to be encoded to a 96-bit RFID tag, the data format MUST also adhere to the “EPC Binary Coding Schemes” outlined in the GS1 EPC Tag Data Standard (TDS).

7.2.4 GDTI: Global Document Type Identifier

The GDTI is a GS1 Identification Key used to identify document types, applicable to paper or digital files, for the purpose of accessing database information that is required for document control purposes.

The GDTI can be combined with an optional serial component, to uniquely identify a specific individual document. For example, the GDTI identifies an appointment follow-up letter, and the serial component will enable identification of the specific letter sent to a patient. For this reason, a GDTI and its serial component is assigned to a single document for its lifetime.

The GDTI uses AI (253) and is a fixed length of 13 numeric characters, including a check digit. See [Appendix 3](#) for more information on check digits. The serial component is variable length, up to a maximum of 17 alphanumeric characters which MAY include all characters contained in [Appendix 2](#). The GDTI MUST adhere to the format shown below.

Figure 15: Format of the GDTI element string

GS1 Application Identifier	Global Document Type Identifier (GDTI)													Check digit	Serial component (optional)
	GS1 Company Prefix						Document type								
2 5 3	N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂	N ₁₃	X ₁ — variable —> X ₁₇	

When indicating this element string in the non-HRI text section of a barcode label, the following data title SHOULD be used: **GDTI**

Figure 16: An example of a GDTI + serial component encoded to GS1-128 barcodes, to identify two different documents of the same type.



Applications where GDTI is allocated by NHS Trusts:

- Patient records, where the GDTI identifies a patient record template, and the serial component identifies each instance of a patient record.
- Letter, where the GDTI identifies a type of letter such as a follow-up, or an appointment confirmation and the serial component identifies the exact letter sent to a specific patient.
- Information leaflet, where the GDTI identifies the type of document such as a fact sheet or marketing brochure and the serial component identifies the specific fact sheet about an ailment, or the marketing brochure for a support group.

Application rules and management practices:

If the function, type, or major content (determined by the document issuer) of the document changes, the document type identifier MUST change. The document issuer will determine if changes to the content of the document require changing the document type identifier or adding or changing a serial component.

The format of the GDTI is at the discretion of the party responsible, but it **MUST** adhere to the structure requirements outlined above.

If the GDTI is to be encoded to a 96-bit RFID tag, the data format **MUST** adhere to the EPC Binary Coding Schemes outlined in the GS1 EPC Tag Data Standard (TDS).

For further information on GS1 Standards for Special Applications such as documents, the “Application Standards” in section 2 of the GS1 General Specifications **MUST** be referred to.

7.2.5 SSCC: Serial Shipping Container Code

The SSCC is the GS1 Identification Key for logistics units of any composition, established for transport and/or storage which needs to be managed, tracked, and traced through the supply chain.

The SSCC is used to uniquely identify packages with their contents such as pallet loads or filled containers and is referenced in documentation giving notice of what will be delivered. The SSCC enables a logistics unit to be directly linked to the relevant delivery information so that it can be received and put away efficiently and so that proof of delivery can be established effectively.

Logistic units MAY be aggregated or nested into other logistic units for part of the journey to the final destination. For example, parcels MAY be combined onto pallets. In that case, the SSCC of the higher logistic unit MAY be used to track and trace the contained logistic units. See the [GS1 Logistics Label Guideline](#) for examples of the way to deal with nested/aggregated logistic units.

The SSCC MUST be encoded to a GS1-128 barcode when printed onto logistics labels. A GS1 DataMatrix MAY also be included in addition to the GS1-128 symbol.

The SSCC uses AI (00) and is a fixed length of 18 numeric characters, including an extension digit and check digit. See [Appendix 3](#) for more information on check digits. The SSCC MUST adhere to the format shown below.

Figure 17: Format of the SSCC element string

GS1 Application Identifier	SSCC (Serial Shipping Container Code)																	
	Extension digit	GS1 Company Prefix							Serial reference							Check digit		
00	N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂	N ₁₃	N ₁₄	N ₁₅	N ₁₆	N ₁₇	N ₁₈


The extension digit is used to increase the capacity of the serial reference within the SSCC. It is assigned by the company that constructs the SSCC. The extension digit ranges from 0-9. When indicating this element string in the non-HRI text section of a barcode label, the following data title SHOULD be used: **SSCC**

Figure 18: An example logistics label with a SSCC encoded to a GS1-128 alongside additional data about the shipment

THE COMPANY LIMITED
ANY ADDITIONAL INFORMATION

SSCC
050123450001234563

Content 15012345678907	Count 110	
Use by 25.12.13	Variant 05	Batch No. 1234AB


(02) 15012345678907 (17) 131225 (37) 0110


(00) 0 5012345 0001234563 (20) 05 (10) 1234AB

Applications where SSCC is allocated by NHS Trusts:

- Identification of consignments of blood product or other biological medical product of human origin (MHRO)⁶. Further information MAY be found in the [GS1 Guidelines for the distribution and shipping of medical product of human origin \(MHRO\)](#)
- To capture and securely share logistics information for the shipping and distribution of medical supplies or equipment

Application rules and management practices:

To ensure global uniqueness and traceability, the physical builder of the logistic unit or the brand owner of the logistic unit is responsible for the allocation of the SSCC. The SSCC is assigned for the lifetime of the transport item and is a mandatory element on the GS1 Logistic Label. Please note that an individual SSCC number MUST NOT be reallocated within one year of the shipment date from the SSCC assignor to a trading partner.

For further information on GS1 Standards for Logistic Units, the “Application Standards” in section 2 of the GS1 General Specifications MUST be referred to.

⁶ Blood and biological medical product of human origin (MHRO) is identified and labelled in accordance with the ICCBBA technical standard ISBT-128.

7.2.6 GIAI: Global Individual Asset Identifier

The GIAI is the GS1 Identification Key for individual assets, such as office equipment, medical devices, surgical instruments, components, and spare parts, but could be anything an organisation owns and needs to manage. GIAIs are used in a diverse range of healthcare applications such as tracking the life-cycle history of surgical instruments or identifying medical assets such as IV pumps.

GIAIs can be encoded to a GS1 barcode or EPC/RFID and applied to items for the purpose of asset management, enabling visibility of records such as history of an item's use and maintenance, its whereabouts, determine its ownership and confirm its warranty status.

The GIAI uses AI (8004) and is a variable length up to a maximum of 30 alphanumeric characters, which MAY include all characters shown in [Appendix 2](#). The GIAI MUST adhere to the format shown below.

Figure 19: Format of the GIAI element string

GS1 Application Identifier	Global Individual Asset Identifier (GIAI)			
	GS1 Company Prefix		Individual asset reference	
8 0 0 4	N ₁ ...	N _i	X _{i+1} ...	X _j (j<=30)

When indicating this element string in the non-HRI text section of a barcode label, the following data title SHOULD be used: **GIAI**

Figure 20: Examples of a label with the GIAI in use



Applications where GIAI could be allocated by NHS Trusts:

- Surgical instruments or equipment, including procedure kit trays and containers used for sterilisation or decontamination services, further information MAY be found in the [GS1 UK Surgical Instrument Traceability Guidance](#)
- Medical or office equipment such as IV pumps and heart monitors or computers and printers

Application rules and management practices:

Asset identifiers MUST NOT be used for any other purpose and MUST remain unique for a period well beyond the lifetime of the relevant records. If a company assigns asset identifiers

to trade items supplied to its customers, the company **MUST** ensure that the asset identifiers are never reused.

All issuers of asset identifiers **MUST** ensure that asset identifiers (GRAIs, GIAIs) allocated for medical devices/equipment used for treatment of a patient **MUST** never be reused. Also, GIAIs that are marked directly on safety critical components and parts, such as used in rail, **MUST** never be reused.

The GIAI is assigned by the owner of the asset and the exact method used to allocate the GIAI is left to the discretion of the issuing organisation. However, each GIAI **MUST** be unique for each individual asset being identified and, for ease of administration, the GS1 system recommends that GIAIs be allocated sequentially and not contain classifying elements.

If the GIAI is to be encoded to a 96-bit RFID tag, the data format **MUST** adhere to the “EPC Binary Coding Schemes” outlined in the GS1 EPC Tag Data Standard (TDS).

For further information on GS1 Standards for Assets, the “Application Standards” in section 2 of the GS1 General Specifications **MUST** be referred to.

7.2.7 GRAI: Global Returnable Asset Identifier

The GRAI is the GS1 Identification Key for returnable asset types that may hold value, such as reusable packages (e.g., gas cylinders) or transport equipment (e.g., pallet or crates). It is used to enable tracking as well as recording of all relevant data associated with the individual asset or asset reference.

Identification of these items helps to manage returnable assets by tracking where they have been sent, determining whether they have been returned, monitoring what they have been used for and recording the history of their maintenance. The GRAI also provides companies with greater supply chain visibility; when a company knows which goods are contained in a particular returnable asset, it can track the asset and, at the same time, track the goods it contains.

The structure of the element string for a Global Returnable Asset Identifier (GRAI) can include two parts: the mandatory identification of an asset type and an optional serial component, to distinguish individual assets within the same asset type.

The GRAI can be encoded in a barcode or EPC/RFID tag that can be scanned to automatically register the returnable asset's movements, for example, when used to ship goods or when returned empty.

The GRAI uses Application Identifier (8003) and is a fixed length of 13 numeric characters, including a check digit. The serial component is variable length, up to a maximum of 16 alphanumeric characters which MAY include all characters shown in [Appendix 2](#) The GRAI MUST adhere to the format shown below.

Figure 21: Format of the GRAI element string

GS1 Application Identifier	Global Returnable Asset Identifier (GRAI)															
	GS1 Company Prefix												Asset type		Check digit	Serial component (optional)
8 0 0 3	0	N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂	N ₁₃	X ₁ – variable → X ₁₆	

When indicating this element string in the non-HRI text section of a barcode label, the following data title SHOULD be used: **GRAI**

Applications where GRAI could be allocated by NHS Trusts:

- Identification of roll cages or trolleys used to transport items throughout a facility
- Identification of gas cylinders or other storage vessels
- Identification of pallets, crates or satchels used to transport items outside the facility

Application rules and management practices:

Asset identifiers MUST NOT be used for any other purpose and MUST remain unique for a period well beyond the lifetime of the relevant records. If a company assigns asset identifiers to trade items supplied to its customers, the company MUST ensure that the asset identifiers are never reused.

All issuers of asset identifiers MUST ensure that asset identifiers (GRAIs, GIAIs) allocated for medical devices/equipment used for treatment of a patient MUST never be reused. Also,

GIAIs that are marked directly on safety critical components and parts **MUST** never be reused for other purposes and must be unique for a period well beyond the lifetime of the relevant asset records.

The GRAI is assigned by the owner of the asset and the exact method used to allocate the GRAI is left to the discretion of the issuing organisation. However, a unique number, the asset type, **MUST** be assigned for each type of asset being identified, and for ease of administration, the GS1 system recommends that numbers be allocated sequentially and not contain classifying elements.

When it is not possible to assign an asset type (e.g., for museum exhibits), or when the type of asset is not required by the application (e.g., when the item is only used for a single type of asset), then the Global Individual Asset Identifier (GIAI), AI (8004), **SHOULD** be used.

If the GRAI is to be encoded to a 96-bit RFID tag, the data format **MUST** adhere to the “EPC Binary Coding Schemes” outlined in the GS1 EPC Tag Data Standard (TDS).

For further information on GS1 Standards for Assets, the “Application Standards” in section 2 of the GS1 General Specifications **MUST** be referred to.

7.2.8 GMN: Global Model Number

The GMN is the GS1 Identification Key used to identify a product model or product family, based on attributes common to the model or family as defined by industry or regulation. Once assigned to a product model or product family, it **MUST NOT** be reissued to another. The GMN **MUST NOT** be used to identify a trade item.

It is unlikely that an NHS Trust will ever need to assign a GMN, so this section is provided for informative purposes only.

Figure 22: UDI regulatory requirements and GS1 Standards table

UDI regulatory requirements	GS1 Standards
Basic UDI-DI Model or product family identifier	GMN (Global Model Number) No Application Identifier (AI) for regulated medical devices
UDI-DI Device Identifier (DI)	GTIN* (Global Trade Item Number) AI (01)
UDI-PI Product Identifier (PI), if applicable PI data will vary by medical device type and manufacturer current practice	AI* Expiration Date AI (17) – e.g., 141122 Batch/lot AI (10) – e.g., 1234AB Serial Number AI (21) – e.g., 12345XYZ Manufacturer data AI (11) – e.g., 250720
* The Human Readable Interpretation (HRI) text format shall follow the rules of the UDI issuing entity	

For regulated healthcare products such as medical devices and in-vitro diagnostic devices, the GMN supports the implementation of “Basic UDI-DI” requirements. The Basic UDI-DI serves as the key element in the UDI regulatory database for medical devices.

By providing an identifier for a medical device product family, the GMN will link medical device trade item(s) identified by GTIN(s) in the UDI database to pre-market and post-market activities (e.g., certificates, declaration of conformity, vigilance, market surveillance and clinical investigations).

Unlike other GS1 Identification Keys, the GMN **MUST NOT** be encoded to a data carrier or EPC/RFID, nor used in any labelling or physical marking, as it is not intended for supply chain identification or transactional purposes.

The GMN is a variable length, up to a maximum of 23 alphanumeric characters which **MAY** include all characters contained [Appendix 2](#), as well as a check character pair. The GMN **MUST** adhere to the format shown below.

Figure 23: Format of the GMN element string

GS1 Application Identifier	Global Model Number (GMN)		
	GS1 Company Prefix	Model reference	Check characters
8 0 1 3	N ₁ ... N _i	X _{i+1} ... variable length X _{j (j<=23)}	X _{j+1} X _{j+2}

When indicating the Basic UDI-DI (GMN) on documents or certificates, the following data title be used: **GMN**. The Application Identifier (AI) 8013 **MUST** be excluded in such documents and certificates.

Application rules and management practices:

For regulated healthcare medical devices, the allocation of the Basic UDI-DI (GMN) is made per the discretion of the brand owner, but in compliance with regulatory rules. Each GMN MUST be unique for each product model or product family being identified and once assigned to one product model or product family, MUST NOT be reissued to identify another product model or product family.

For further information on GS1 Standards for Special Applications such as the Global Model Number, the “Application Standards” in section 2 of the GS1 General Specifications MUST be referred to.

7.3 GS1 Application Identifiers

Application Identifiers (AI) are 2, 3 or 4-digit numbers which define the meaning and the format of the data that follows, allowing scanners and systems to unambiguously interpret the data that follows each AI.

Als are a fundamental part of the GS1 data syntax and **MUST** be used when encoding GS1 Identification Keys and any supplementary attribute data to GS1 Data Carriers.

Key Concepts:

- More than one AI can be encoded to a single barcode. This is known as concatenation.
- When structuring data in concatenated barcodes, Als with fixed length data content (e.g., SSCC has a fixed length of 18 digits) **SHOULD** be placed at the beginning and Als with variable lengths (e.g., serial number) **SHOULD** be placed at the end.
- If more than one variable length AI is placed in one barcode, a Function 1 (FNC1) separator character **MUST** be used to tell the scanner system when one data item ends and the other one begins. No FNC1 is needed at the end of the last data item in a string. Further information on the FNC1 character can be found in [Appendix 4](#).
- To enable the production of smaller barcodes, some Als and their content (known as element or data strings) have been predefined in length, so that their end is determined. These element strings are shown in the predefined length table in [Appendix 5](#) and do not require any FNC1 separator character.

Figure 24: Some key supplementary attributes used across the Healthcare sector

Application Identifier (AI)	Data content	Format ⁷	FNC1 required	Data title
10	Batch or lot number	N2+X..20	Yes	BATCH/LOT
11	Production date	N2+N6	No	PROD DATE
17	Expiration date	N2+N6	No	USE BY or EXPIRY
21	Serial number	N2+X..20	Yes	SERIAL
7240	Protocol ID (used for clinical trials)	N4+X..20	Yes	PROTOCOL
8019	Service relation instance number	N4+N..10	Yes	SRIN

For the complete list of GS1 Application Identifiers, including compliance requirements for data format, FNC1 and data titles, “GS1 Application Identifier Definitions” in section 3 of the GS1 Specifications **MUST** be referred to.

⁷ The first position indicates the length (number of digits) of the GS1 Application Identifier. The following value refers to the format of the data content. The following convention is applied:

- N numeric digit
- X alphanumeric characters
- N3 3 numeric digits, predefined length
- X3 3 alphanumeric characters, fixed length
- N..3 up to 3 numeric digits
- X..3 up to 3 alphanumeric in figure

7.4 Data Relationships

This section outlines the rules for mandatory and invalid combinations of element strings on the same physical entity, irrespective of the data carrier(s) applied to the entity. These rules are application neutral, meaning they apply wherever multiple element strings are combined.

7.4.1 Invalid Pairs of Element Strings

Invalid pairs of element strings are element strings which **MUST NOT** appear together on the same physical entity.

- Multiple AIs may be listed in the first or third column, separated by commas. This means that the same rule applies to all listed AIs.
- The rules work in both directions, e.g., if it states AI (01) **MUST NOT** be combined with AI (37) this implies that AI (37) **MUST NOT** be combined with AI (01).

Figure 25: An excerpt of the invalid pairs of element strings table, with some common healthcare care element strings shown as an example.

Invalid pairs of element strings				Rule
AI	Designation	AI	Designation	
01	GTIN	01	GTIN	All occurrences of GTIN MUST have one value. It is for example not allowed to include GTINs of other packaging levels.
01	GTIN	02	GTIN of contained trade items	GTIN of contained trade items is intended to list the trade items contained in a logistic unit, and MUST NOT be used to identify the contents of a trade item.
01	GTIN	37	Count of units contained	The count of units contained MUST only be used with GTIN of contained trade items or trade item pieces.
21	Serial Number	235	Third Party Controlled, Serialised Extension of GTIN	Only Serial Number or Third Party Controlled, Serialised Extension of GTIN MUST be used with GTIN.
8018	GSRN for the recipient	8017	GSRN for the provider	Only one Global Service Relation Number (recipient or provider) MUST be applied at one time for identification of an individual in a given service relationship
8026	Identification of a trade item piece contained in a logistic unit	02, 8006	GTIN of contained trade items, Identification of an individual trade item piece	Identification of the trade item piece contained in a logistic unit MUST NOT be used in combination with GTIN of contained trade items or identification of an individual trade item piece.

To view the full table of invalid pairs of element strings, “Data Relationships” in section 4 of the GS1 General Specifications **MUST** be referred to.

7.4.2 Mandatory Association of Element Strings

Mandatory pairs of element strings are element strings which **MUST** appear together on the same physical entity. This does not necessarily mean that the element strings need to appear in the same data carrier. For example, multiple GS1-128 barcode symbols **MAY** be used in combination on a GS1 Logistic Label.

- The table is sorted by AI value, with the AI that is the trigger for the rule displayed in the first column. This means that this table cannot be read in both directions. For example, a rule that states AI (17) MUST be used together with AI (01), does not imply that AI (01) can only be used together with AI (17), since it can also be used with other AIs.
- Multiple AIs may be listed in the first column, separated by commas. This means that the rule applies to all the listed AIs (element strings).
- The same AI can occur in the first column multiple times, in different rows. This means that depending on the value of the element string, different rules need to be applied.
- When multiple AI are included in the third column, this is always done with an AND, OR or XOR logical operator between them:
 - AND means that all element strings MUST appear on the physical entity
 - OR means that one or a combination of the element strings MUST appear on the physical entity.
 - XOR means that one of the element strings MUST appear on the physical entity, and the other element string MUST NOT.

Figure 26: An excerpt of the table, with some common healthcare care element strings shown as an example.

If element string		Then mandatory associated element string	Rule
AI	Designation	AI	
02	GTIN of contained trade items	00 AND 37	The GTIN of contained trade items MUST occur in combination with an SSCC and the count of the trade items.
10	Batch/lot number	01 XOR 02 XOR 8006 XOR 8026 ***	Batch/lot number MUST occur in combination with: <ul style="list-style-type: none"> ■ a GTIN; or ■ a GTIN of contained trade items; or ■ an ITIP ■ an ITIP of contained trade item pieces
11, 13, 15, 16, 17	Production date, packaging date, best before date, sell by date, expiration date (of a trade item)	01 XOR 02 XOR 8006 XOR 8026 ***	These dates MUST occur in combination with: <ul style="list-style-type: none"> ■ a GTIN; or ■ a GTIN of contained trade items; or ■ an ITIP ■ an ITIP of contained trade item pieces
21	Serial number	01 XOR 8006***	The serial number MUST occur in combination with: <ul style="list-style-type: none"> ■ a GTIN; or ■ an ITIP Note: SGTIN is a common term for the combination of GTIN and serial number.
254	GLN extension component	414	The GLN extension component MUST occur with the Identification of a physical location (GLN).
415	GLN of the invoicing party	8020	The GLN of the invoicing party MUST occur in combination with the payment slip reference number.
430N	Ship-to / Deliver-to address GS1 Application Identifiers	00	Ship-to / Deliver-to address GS1 Application Identifiers MUST occur in combination with an SSCC
4303	Ship-to / Deliver-to address line 2	4302 and 00	Ship-to / Deliver-to address line 2 MUST occur in combination with line 1 of a ship-to address and an SSCC

If element string		Then mandatory associated element string	Rule
AI	Designation	AI	
431N	Return-to address GS1 Application Identifiers	00	Return-to address GS1 Application Identifiers MUST occur in combination with an SSCC
4313	Return-to address line 2	4312 AND 00	Return-to address line 2 MUST occur in combination with line 1 of a return-to address
7003	Expiration date and time	01 XOR 02	The expiration date and time MUST occur in combination with: <ul style="list-style-type: none"> ▪ a GTIN; or ▪ a GTIN of contained trade items.
7004	Active potency	01 AND 10	The active potency MUST occur in combination with the batch/lot number and the GTIN.
7240	Protocol ID	01 XOR 8006	The protocol ID MUST occur in combination with a GTIN
8008	Date and time of production	01 XOR 02	The date and time of production MUST occur in combination with: <ul style="list-style-type: none"> ▪ a GTIN; or ▪ a GTIN of contained trade items.
8019	Service Relation Instance Number	8017 XOR 8018	The Service Relation Instance Number MUST occur in combination with: <ul style="list-style-type: none"> ▪ the GSRN for the provider; or ▪ the GSRN for the recipient.

To view the full list of mandatory association of element strings, “Data Relationships” in section 4 of the GS1 General Specifications MUST be referred to.

8 GS1 Data Carriers

GS1 Identification Keys and supplementary attribute data are used with a range of GS1 Data Carriers, most commonly GS1 barcodes but also Radio Frequency Identification (RFID) tags, encoded with an Electronic Product Code™ (EPC). It is important to note that GS1 Identification Keys are defined independently of the barcode or RFID tag in which they are encoded. In other words, GS1 Standards data has the same meaning, regardless of the technology in which it is carried.

The current version of this specification includes four data carriers commonly used within the Healthcare sector:

- GS1 DataMatrix (2D barcode)
- GS1-128 (1D linear barcode)
- EAN-13 (1D linear barcode)
- EPC/RFID

The following sections describe a concept of use and an overview of the key features, technical characteristics, and requirements of each GS1 Data Carrier.

For further information on the data carriers outlined below and the full range of GS1 Data Carriers, the “Data Carriers” in section 5 of the GS1 General Specifications MUST be referred to.

8.1 GS1 DataMatrix

The GS1 DataMatrix is a two-dimensional (2D) barcode symbol which can encode large amounts of data in a small space. With in-built error correction capabilities, the GS1 DataMatrix is increasingly the symbol of choice for many in healthcare, not only due to its size and data capacity, but also its resilience to damage.

For regulated healthcare products such as medicines and pharmaceuticals or medical devices for example, the GS1 DataMatrix can be used as it can hold important supplementary attribute data such as expiry dates, batch/lot numbers and serial numbers, which can be captured alongside the GTIN. This enables visibility of stock for improved inventory management, but also for caregivers to ensure medical supplies are correct and safe for use.

Additionally, GS1 DataMatrix symbols are the only symbol approved for direct part marking of surgical instruments or implantable devices as it can be etched directly into metals and other substrates but remains readable despite wear and tear.

Key Features

- The GS1 DataMatrix is a subset of the ECC 200 Data Matrix symbol, which is defined by international standards *ISO/IEC 16022*.
- As a 2D barcode, an optical or camera-based scanner capable of omni-directional scanning is required (also known as imaging scanners or vision systems).
- Uses Reed-Solomon error correction, which enables the barcode to withstand typically up to 25% damage and still allow for successful scanning.

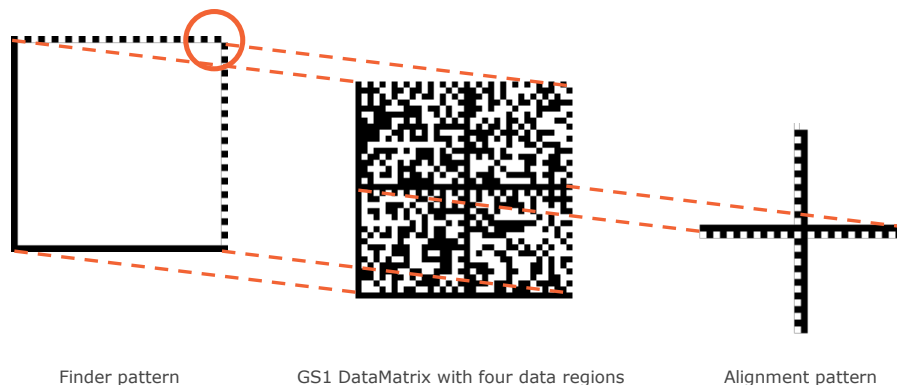
- Can be produced in square or rectangular formats, however the square format is most commonly used as it has a larger range of sizes to accommodate the encoding of large amounts of data.
- Square format can encode a maximum of 2335 alphanumeric characters or 3116 numeric digits.
- Square format can be produced at a minimum of 10x10 modules and a maximum of 144x144 modules.
- Can be printed dark on light, or light on dark.

Technical characteristics & requirements

The GS1 DataMatrix MUST include the following:

- “L-shaped” and “clock-track” finder pattern
- The top right corner is always a white square (or the colour of the background, if printed as light on dark), as this indicates the symbol is an ECC200 symbol
- Larger, square formats (at least 32x32 modules) will include alignment patterns to separate the data regions

Figure 27: GS1 DataMatrix with four data regions shown alongside its finder pattern and alignment patterns



- Quiet zone with one module width (1x), on all four sides of the GS1 DataMatrix
- MUST include a special start sequence (also known as a start character) to differentiate a GS1 DataMatrix from other ISO/IEC Data Matrix symbols. This is achieved by using the Function 1 Symbol Character (FNC1) in the first position of the data encoded. See [Appendix 4](#) for further information on FNC1.
 - When a barcode scanner detects the FNC1 start character in the first position of the encoded data, it transmits the symbology identifier **jd2**. This indicates the symbol is a GS1 DataMatrix, which enables scanners to clearly understand and process the information according to GS1 Standards.
- Supports concatenation, enabling multiple element strings (i.e., Application Identifiers (AI) and their data) to be encoded into a single symbol, as explained in [Section 7.3](#).

For further information on the production and use of GS1 DataMatrix symbols, the GS1 DataMatrix Guidelines and “Data Carriers” in section 5 of the GS1 General Specifications MUST be referred to.

8.2 GS1-128

The GS1-128 is a one-dimensional (1D) linear barcode symbol widely used for general distribution purposes, such as for logistics units or outer cases, as it can encode additional supplementary data as concatenated data strings, if required. It is also used for any applications that do not cross retail point-of-sale. Within healthcare settings, a GS1-128 can often be found on documents, location labels and even sterilised surgical instrument kits.

Key Features

- The GS1-128 is a subset of the Code 128 linear barcode symbol, which is defined by international standards *ISO/IEC 15417*.
- As a 1D barcode, both a laser scanner or an optical/camera-based scanner can be used. Any scanner capable of reading GS1 DataMatrix can also read linear barcodes as well.
- The maximum physical length, including Quiet Zones is 165.10 millimetres (6.500 inch). The barcode can be printed wider than this, but laser scanners are unable to decode any symbols greater than this width.
- Can encode a maximum of 48 alphanumeric characters.

Technical characteristics and requirements

The GS1-128 barcode MUST be made up as follows, reading from left to right:

- Left Quiet Zone
- The double character start pattern:
 - A start character (A, B, or C)
 - The Function 1 Symbol Character (FNC1)
- Data (including the GS1 Application Identifier represented in character set A, B, or C).
- A symbol check character.
- The stop character.
- Right Quiet Zone.

Figure 28: General format of a GS1-128 barcode



- The GS1-128 symbol **MUST** include a special double character start pattern consisting of start character (A, B, or C) and the Function 1 Symbol Character (FNC1).
 - These special start characters differentiate GS1-128 barcodes from the more generalised Code 128 symbols, by transmitting the symbology identifier **1C1**. This enables scanners to clearly understand and process the information according to GS1 Standards.
- Start characters A, B, and C define the corresponding code set to be used initially in the symbol
 - **Code set A** includes all of the standard upper case alphanumeric characters and punctuation characters together with the symbology elements (e.g., characters with ASCII values from 00 to 95) and seven special characters.
 - **Code set B** includes all of the standard upper case alphanumeric characters and punctuation characters together with the lowercase alphabetic characters (e.g., ASCII characters 32 to 127 inclusive) and seven special characters.
 - **Code set C** includes the set of 100-digit pairs from 00 to 99 inclusive, as well as three special characters. This allows numeric data to be encoded as two data digits per symbol character. Start character C **SHOULD** always be used when the data inclusive of the AI begins with four or more numeric characters.
- Supports concatenation, enabling multiple element strings (i.e., Application Identifiers (AI) and their data) to be encoded into a single symbol, as explained in [Section 7.3](#).

For further information on the production and use of GS1-128 symbols, “Data Carriers” in section 5 of the GS1 General Specifications **MUST** be referred to.

8.3 EAN-13

The EAN-13 barcode is a one-dimensional (1D) linear barcode symbol, and is the UK's most common barcode, typically found on products being scanned at retail point-of-sale, including branded pharmaceutical products. It's unlikely that an EAN-13 barcode will be produced in a healthcare setting, as it has a limited data capacity and is usually applied to product packaging by a manufacturer.

Key Features

- The EAN-13 is part of the EAN/UPC symbology family, which is defined by international standards *ISO/IEC 15420*.
- It can only encode a 13-digit GTIN and cannot carry any other GS1 Identification Key or attributes.
- As a 1D barcode, both a laser scanner or an optical/camera-based scanner can be used. Any scanner capable of reading GS1 DataMatrix can also read linear barcodes as well.

Technical Characteristics and requirements

The EAN-13 barcode MUST be made up as follows, reading from left to right:

- A left Quiet Zone.
- A normal guard bar pattern.
- Six symbol characters from number sets A and B (i.e., numeric characters 0 to 9 only).
- A centre guard bar pattern.
- Six symbol characters from number set C (i.e., numeric characters 0 to 9 only).
- A normal guard bar pattern.
- A right Quiet Zone.

Figure 29: General format of an EAN-13 barcode



For further information on the production and use of EAN-13 barcodes, “Data Carriers” in section 5 of the GS1 General Specifications **MUST** be referred to.

8.4 Radio Frequency Identification (RFID)

Radio-Frequency Identification (RFID) is a type of automatic identification and data capture (AIDC) technology which uses radio waves to read and obtain information stored on an RFID tag.

An RFID system consists of readers and tags, where the RFID reader sends out a signal that picks up any RFID tags within its range. The RFID tag responds by sending back a signal carrying data.

For this reason, RFID is quite often used to track and manage assets such as medical equipment, objects such as patient files, or even people such as caregivers or patients, that may need to move throughout healthcare facilities.

Key Features

- RFID tags are a type of data carrier which do not require an optical line-of-sight to be read, unlike traditional 1D or 2D barcode symbols. Instead, data is transmitted as radio waves via battery-less antennas.
- RFID tags store unique identifiers such as serial numbers, on a microchip that is attached to an antenna (the chip and the antenna together are known as the RFID tag, sometimes referred to as an RFID transponder).
- Multiple tags can be read at once, at an average of 100+ tags per second
- Durability – some tag types can be permanently attached to assets
- Items can be tracked throughout the entire supply chain, including the patient pathway
- RFID tags are often accompanied by barcodes, to address regulatory requirements which dictate the need for optical data carriers in certain applications such as for medical devices.

Technical Characteristics and requirements

Identification – EPC/RFID: GS1 Standards provide the specification of the Electronic Product Code™ (EPC) and memory contents of Gen 2 RFID tags.

- EPC/RFID is a subset of RFID technologies used within the GS1 system. This allows any physical object that is already identified by a GS1 Identification Key (or GS1 key + serial number combination) to be used in an EPC context where any category of physical object may be observed.
- The EPC is a universal identifier that provides a unique identity for any physical entity, such as an object, location or even a person. The EPC is designed to be unique across all physical entities in the world, over all time, and across all categories and is expressly intended for use by business applications for tracking purposes.
- For further information on how GS1 Identification Keys are represented for use in RFID tags, the “EPC Binary Coding Schemes” section in the [GS1 EPC Tag Data Standard \(TDS\)](#) MUST be referred to.

EPC/RFID Tags – Air Interface Protocol: There are two types of EPC/RFID data carriers optimised for different GS1 application requirements. Both are passive, battery-less

technologies and are designed to carry GS1 Identification Keys and Application Identifiers, in an EPC format.

- The first type, UHF EPC/RFID, works in the UHF (Ultra High Frequency) bands 860 MHz – 960 MHz and is defined in the “[EPC UHF Gen2 Air Interface Protocol Standard](#)”. This standard has established itself as the backbone for UHF RFID implementations across multiple sectors.
- The second type, HF EPC/RFID, works in the HF (High Frequency) band 13.56 MHz and is defined in the “[EPC Class-1 HF RFID Air Interface Protocol Standard](#)”.
- GS1’s Air Interface Protocol Standards define the way readers and tags make use of a dedicated frequency band of the radio spectrum to communicate and outlines a set of standardised commands and responses, including a number of backwards-compatible, optional features.

It is worth noting that the choice of any of the available RFID technologies, is globally independent from the data and identifiers that the RFID tags carry.

The full suite of GS1 Standards which complement the GS1 EPC Tag Data Standard (TDS), such as the EPC/RFID Air Interface protocols described here, SHOULD be referred to at the [GS1 RFID Standards homepage](#).

8.5 Data Carrier Management

The main reason for using data carriers such as barcodes or RFID is to replace manual entry of visually captured data, enabling greater efficiency and accuracy.

The following sections provide a summary of the key data carrier management guidelines and best practices provided by GS1 Standards, to ensure that once data carriers are produced, they can be applied correctly to serve their intended purpose.

8.5.1 Symbol Placement Guidelines

Consistency of symbol placement is critical to successful scanning. With manual scanning, variation of symbol placement makes it difficult for the scanning operator to predict where the symbol is located, and this reduces efficiency.

With automated scanning, the symbol **MUST** be positioned so that it will pass through the field of vision of a fixed scanner as it travels past. Respecting the guidance outlined by GS1 Standards will result in the consistency and predictability required.

If government regulatory guidelines are inconsistent with those in this document, government guidelines **SHOULD** always take precedence.

- Barcodes representing different Global Trade Item Numbers (GTINs) **MUST** never be visible on any one item.
- Barcode orientation for linear symbols, are determined primarily by the print process and any curvature of the item. If the printing process and curvature allow, the preferred placement is picket fence orientation, in which the bars of the barcode are perpendicular to the surface on which the package stands in its normal display position. If the package diameter is too small to permit a picket fence orientation barcode, the symbol **MUST** be rotated 90 degrees to a ladder orientation. Please refer to [Appendix 6](#) for further information on picket fence and ladder orientation.
- Anything that will obscure or damage a barcode will reduce scanning performance and **MUST** be avoided. For example:
 - Never position the barcode on the item in an area with inadequate space. Do not let the other graphics encroach on the space for the barcode.
 - Never place barcodes, including Quiet Zones, on perforations, die-cuts, seams, ridges, edges, tight curves, folds, flaps, overlaps, and rough textures.
 - Never put staples through a barcode or its Quiet Zones.
 - Never fold a symbol around a corner.
 - Never place a symbol under a package flap.

For the complete set of application specific rules, such as use in General Distribution or for Logistics Labels, “Symbol Placement Guidelines” in section 6 of the GS1 General Specifications **MUST** be referred to.

8.5.2 Multiple Barcode Management Practices

When additional barcodes are introduced into an existing scanning environment or business application, existing barcodes **MUST** remain acceptable. GS1 Standards provides a set of multiple barcode management practices, which are intended to permit the use of multiple barcodes on the same package. Below are some key practices:

- **Adjacent placement:** Wherever two symbols can be used for the same application they **SHOULD** be placed adjacent to one another. Adjacent placement of symbols **MUST** never infringe on symbol Quiet Zones. Where adjacent placement on one panel is not permitted based on space limitations, placement on adjacent panels **SHOULD** be attempted.
- **Non-adjacent placement:** Wherever two symbols are used for different applications, they **SHOULD** be placed non-adjacent to one another.
- **Obscure placement:** Wherever a symbol is used for production control purposes only, it **SHOULD** be made as obscure as possible or even obstructed on the trade item package.

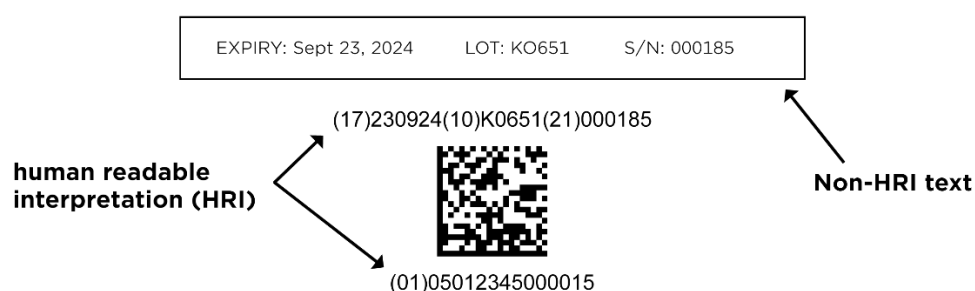
For the complete set of application specific guidelines, including the additional rules which apply to regulated healthcare items scanned at both retail pharmacy and non-retail pharmacy/bedside, “Multiple Barcode Management Practices” in section 4 of the GS1 General Specifications **MUST** be referred to.

8.5.3 Human Readable Interpretation (HRI) Rules

Human Readable Interpretation (HRI) rules are provided to standardise printing requirements and facilitate training of staff on how to deal with GS1 Data Carriers that fail to scan or read. GS1 Standards provides guidance on two types of text that appear on a label, package, or item:

- **Human readable interpretation (HRI):** is the information below, beside or above a barcode or tag, which is encoded in the barcode or tag and represents the same characters as carried in the barcode or tag.
- **Non-HRI text:** is all other text on package, label or item.

Figure 30: Example of HRI and non-HRI text



Below are some key HRI rules (exceptions MAY occur only when local regulatory or legal requirements mandate otherwise):

- Whether a GS1 AIDC data carrier encodes a GS1 Identification Key, attributes, or a combination of both, the HRI SHOULD be placed below the barcode and grouped together wherever physically possible while maintaining the HRI legibility and minimum barcode height.
 - In cases where the HRI needs to be printed above, to the left, or to the right of the symbol due to packaging or space constraints, HRI MUST always be printed adjacent to (obviously associated with) the GS1 AIDC data carrier while protecting Quiet Zones.
 - If the HRI for GS1 Identification Keys and attributes is split (for example GS1 key HRI is below the barcode and GS1 attributes HRI is above the barcode), the preference for GS1 key HRI placement is always below the barcode.
 - When HRI is grouped together (for example, all HRI data is grouped below the barcode or all HRI data is grouped above the barcode), HRI MUST always follow the encoding sequencing of the GS1 AIDC data carrier.
- A single data element MUST NOT be broken into two lines of HRI, for example the data for a serial number would appear on one line of HRI.
- Parentheses MUST surround AIs in HRI but MUST NOT be encoded in the GS1 Data Carrier.
- HRI MUST be limited to element strings and will not include GS1 AIDC data carrier overhead such as separator characters.
- HRI MUST appear except in rare circumstances for specific applications where there are extreme space constraints (e.g., direct part marking). If the GS1 Data Carrier cannot be read or scanned and the HRI does not appear on the label, package, or item, non-HRI text SHOULD be used as backup information.
- As a non-HRI text option, a data title MAY be associated with the data instead of using the AI numbers. Data titles are explained in [section 7.2 for each GS1 Identification Key](#) and in [section 7.3 GS1 Application Identifiers](#).

For the complete set of rules including application specific guidance for use in healthcare, “Human Readable Interpretation (HRI) rules” in section 4 of the GS1 General Specifications MUST be referred to.

9 Barcode Production

GS1 provides Application Standards that define which GS1 Identification Keys SHOULD be used with which GS1 Data Carriers, for the required scan environment. The following section provides an overview of how to choose the right data carrier and ensure it is produced and printed to meet compliance to GS1 Standards.

9.1 Choosing the Right Data Carrier

To choose the right data carrier, it's important to clearly understand the intended use and scan environment required, as well as the type of data needed for the application.

For example, at point-of-sale (POS), a GTIN is needed to look up a price so that the item can be charged to the customer. Therefore, only an EAN-13 is needed, as no further data beyond a GTIN will be processed.

For inventory management or traceability purposes, information such as batch/lot number, serial number or expiry date may be needed as well as the GTIN, so a GS1-128 or GS1 DataMatrix symbol may be used. Both symbols can accommodate lots of data, however if the scan environment can only operate a traditional laser scanner, such as with older infrastructure, a GS1-128 symbol will need to be used as a GS1 DataMatrix can only be read by a camera-based scanner. Alternatively, if the item which requires the barcode is very small, a GS1 DataMatrix would be more suitable as a GS1-128 symbol encoded with additional data simply will not fit.

For asset tracking, RFID may be most suitable, as the technology enables the data carrier encoded with a GIAI or GRAI to be read without any line of sight, unlike a barcode, which needs to be physically available to be scanned and read. As the RFID tagged item moves throughout a facility, its movement can be captured each time it passes a reader, enabling real time visibility of the item's last recorded whereabouts.

So, it's important to reference GS1 Application Standards to ensure the correct GS1 Identification Key and most suitable GS1 Data Carrier is used. Additionally, GS1 Application Standards define the required symbol size and quality specifications required for the intended scan environment. The following sections provide an overview of GS1 Application Standards and Symbol Specification Tables.

9.1.1 GS1 Application Standards

GS1 Application Standards enable users to select and produce the most appropriate GS1 Data Carrier for their intended purpose, with the following important information:

- Required GS1 Identification Key, including references to data format and allocation rules
- Required or optional data attributes
- Data carrier specifications
 - Data carrier choices
 - Symbol specification table references
 - Symbol placement references

- References to processing requirements

Some key GS1 Applications Standards used in healthcare include:

- Trade items – Healthcare primary packaging (non-retail trade items): used for pharmaceutical and medical products to support point-of-care dispensing. Only marked when the package is intended for dispensing to the consumer in a hospital or equivalent facility, such as with clinical trials or sterile/decontamination service labelling.
- Trade items – Healthcare secondary packaging (regulated healthcare retail consumer trade item): not intended to be scanned in high volumes per consumer transaction at retail but does require additional data beyond GTIN to support regulatory requirements e.g., certain regulated pharmaceuticals sold at point-of-sale.
- Trade items – Medical devices (non-retail trade items): used for direct part marking (DPM) of medical devices and surgical instruments.
- Logistics units: used for shipping and distribution of general supplies as well as biological products.
- Assets: used for the management of assets such as computers or oxygen tanks for example.
- Locations and parties: used to manage identification of various physical locations and organisational parties or entities.
- Service relationships: used to manage identification of service providers such as care staff, and recipients such as patients
- Document control: used to manage different types of physical and digital documents, including specific instances of documents.

For further information, “Application Standards” in section 2 of the GS1 General Specifications MUST be referred to.

To find the correct GS1 Application Standard for the required scan environment, the “*Summary of applications and operative scanning environments*” table in section 2 of the GS1 General Specifications MAY be referred to.

9.1.2 GS1 Symbol Specification Tables

GS1 Symbol Specification Tables define the required size specifications and minimum overall symbol quality needed for each GS1 Data Carrier to function optimally, and consistently, in respect to the intended area of application.

The key specifications provided include the following:

- **X-dimension**: for linear barcodes, the X-dimension is the width of the narrowest bar. For 2D barcodes, the X-dimension is the width and height of one cell, or module.
- **Symbol height**: is the overall height of the barcode symbol, from top to bottom, excluding the quiet zone or any HRI text.
- **Quiet zone**: is the clear space on the left and right sides of a linear barcode, and around all four sides of a 2D barcode.

- **Minimum quality specification:** is the minimum overall symbol quality grade and verification settings required to meet compliance to GS1 Standards for the chosen data carrier and application.

GS1 Data Carriers MUST be produced in accordance with the dimensions and allowances provided in the “GS1 Symbol Specification Tables” in section 5 of the GS1 General Specifications.

Details of the correct GS1 Symbol Specification Table(s) required for the intended scan environment is detailed the GS1 Application Standard, as explained in [section 9.1.1](#) above.

To select the correct Symbol Specification Table for the intended application the “*GS1 symbology operational environment decision tree*” diagram in section 5 of the GS1 General Specifications MAY also be referred to.

9.2 Printing Considerations

The functional and operative bands provide printers and labellers with the flexibility needed to produce quality symbols over a wide range of processes. Once a scanning operational environment is determined and the allowable specification range is known, the printer should be consulted for guidance on:

- The minimum recommended symbol size based on printing press or print characterisation tests.
- Colour/substrate considerations (e.g., separate print station for symbol or double ink layer).
- The optimum orientation of the symbol on the printed web (the direction of movement of the media in relation to a printing plate on a printing press).
- Direct part marking, such as is done by dot peening on items, requires special considerations for material properties.
- Laser or chemically etched parts with low contrast or light marked elements on a dark background (e.g., medical instruments, surgical implants).
- High-speed ink jet printed parts and components where the marked dots cannot form a scannable linear symbol.
- Very small items that require a symbology with a square aspect ratio and/or cannot be marked within the allocated packaging space by existing GS1 DataBar and Composite symbols.

To find out more on whether your use case requires thermal transfer, inkjet, laser coding or impact marking (dot peening), please visit the [Partner Finder](#) for a list of solution provider who can provide recommendations.

10 Data Carrier Quality and Compliance

The accurate printing of barcodes is fundamental to successful scanning. Therefore, barcode production **MUST** also include robust validation and verification practices to ensure quality and compliance checks are a standard part of the process.

Barcode scanning itself, provides no indication of barcode quality, as it gives no information about the symbol other than whether it can be read or not by that specific scanner. Scanners simply look for the contrast between the light and dark spaces to decode the different widths and extract the data which is sent to the software for processing.

Verification confirms the overall symbol quality and can provide an assurance that the barcode can be scanned and read by all types of scanners, in various conditions, without fail. GS1 Standards defines the ideal dimensions and minimum symbol quality specifications, required to produce optimum barcodes for the intended use or application, in line with global standards ISO/IEC 15416 (for linear symbols) and ISO/IEC 15415 (for 2D symbols).

Ideally, staff managing the production of barcodes **SHOULD** be trained to use ISO/IEC compliant verification equipment to check that any new or amended solutions provided by trading partners are compliant to global standards, ahead of go-live or roll-out. However, as part of the renewed GS1 UK membership contract for all NHS Trusts in England, validation and verification support is available to all NHS Trusts in England.

Further details to confirm compliance to GS1 Standards and obtain a GS1 Compliance Certificate are outlined in the sections below.

10.1 Barcode Validation

Barcode validation is a preliminary sense check that reviews the barcode symbol type and the data encoded to it, to ensure that both the data carrier and data in it (i.e., the data structure) is valid and compliant to GS1 Standards for the intended application.

Barcode validation is carried out on a soft copy barcode sample, which **MAY** be a photo, scan, or image file of the barcode label, wristband sample, or simply the barcode itself. Soft copy samples **MUST** be a high-quality image, without blurring, pixilation, or any type of distortion.

All barcode samples **SHOULD** pass validation before a physical sample is produced and sent in for verification.

10.2 Barcode Verification

Verification measures the physical production quality of the barcode by providing a grade to indicate the overall symbol quality, and is the final, formal step to confirming full compliance to GS1 Standards. For this reason, verification **MUST** be carried out on a physical sample of the barcode label or wristband sample, in its **finished configuration**. If any part of the barcode production process is altered, such as a change to the print technique or equipment, material/substrate type, or any re-design or re-configuration of the barcode label, a new physical sample **SHOULD** be re-submitted for verification.

It's important to note that a verifier is not the same as a barcode scanner. A scanner simply decodes a barcode to read what has been encoded to it. Whereas a verifier is a measuring tool which can assist in diagnosing problems with a barcode symbol by assessing the

physical production characteristics of the barcode, in accordance with global standards and GS1 Symbol Specification Tables. These parameters and specifications are outlined in the following sections.

For further information on verification, Quality Assessment in section 5 of the GS1 General Specifications MUST be referred to.

10.2.1 Print Parameters

Print parameters are measured and graded separately, in accordance with the criteria defined by global standards ISO/IEC 15416 and ISO/IEC 15415. The grade given to the barcode, is the lowest score for any one of these parameters.

The following print parameters are graded for both 1D and 2D symbols:

- **Decode:** an indication that the symbol will decode successfully if it conforms to the specifications, notably in respect of character encodation, check digits and quiet zones.
- **Symbol contrast:** a measure of the contrast difference between the dark bars or modules, and the paler background.
- **Modulation:** a ratio of the minimum edge contrast to the symbol contrast. This grade will be low if positive bar gain has increased the width of the bars causing a narrowing of the spaces between them.

The following print parameters are graded for 1D symbols only:

- **Minimum reflectance:** a check that the bars appear dark enough in relation to the spaces.
- **Minimum edge contrast:** a measure of the least difference in contrast between an adjacent bar and space. This will be a low grade if the barcode is unlikely to be read when it is scanned.
- **Defects:** which may be light voids within dark bars or dark spots in the spaces between the bars.
- **Decodeability:** an indication of the accuracy of widths and positions of the bars and spaces.

The following print parameters are assessed for 2D symbols only:

- **Axial nonuniformity:** a measure of the module center spacing and uneven scaling of the symbol along the X or Y axis.
- **Grid nonuniformity:** a measure of the largest deviation of grid intersections, determined by the theoretic position prescribed by the reference decode algorithm and the actual measured results.
- **Unused error correction:** measures and grades the reading safety margin that error correction provides. Error correction is a method of reconstructing data that is lost via damage, erasure of the symbol or poor printing. Unused error correction indicates the amount of available error correction in a symbol, with 100% being ideal.

- **Fixed pattern damage:** a measure of any damage to the Finder Pattern, Clock Track and quiet zone of the symbol.
- **Print growth:** measures how symbols may have grown or shrunk from the target size. Print growth may be measured independently on both the X and Y axis to assess both horizontal and vertical growth or shrinkage. Print growth is not a graded parameter but is an informative measure used for the purposes of process control.

10.2.2 GS1 Specifications

Different symbol size specifications are provided for different applications, based on their intended use and scan environments. These requirements are defined by the GS1 Symbol Specification Tables, and outline the different thresholds allowed for each of the following:

- X-dimension
- Symbol height
- Quiet zones
- Minimum overall symbol quality

An explanation of these symbol specifications is provided in the Barcode Production [section 9.1.2](#) of this document.

10.3 RFID Tag Validation

RFID tags can only be validated (not verified) with a physical sample as it's only the data format of the tag content which is checked for compliance to GS1 EPC Tag Data Standards (TDS).

If the RFID tag is also barcoded, the barcode validation and verification process **MUST** be followed, meaning a soft copy sample of the barcode **SHOULD** be submitted for validation first, ahead of sending any physical sample for verification.

10.4 Validation and verification support for NHS Trusts

To request validation or verification support, please send an email to healthcare@gs1uk.org with the information below:

- Trust name
- Trust contact name and details
- Type of barcode label for review
- For validation, provide a high-quality image of the sample in either PDF, JPG or PNG format.
- For verification, advise whether the physical sample is a 1D or 2D barcode, and/or a RFID tag

Once this information has been provided, the address where the sample is to be sent will be confirmed.

If the physical sample is deemed compliant to GS1 Standards, the following information about the system(s) being used to create the barcode and/or RFID tag will be requested:

- ***System Name:***
- ***System Version:***
- ***System Description:***

When this information has been received, GS1 UK will issue a GS1 Compliance Certificate to the Trust.

11 Helpdesk

11.1 Contact Information

For further information and support on the DAPB0108: AIDC information standard, please note the following details:

Developer	
Organisation	GS1 UK
Email Address	healthcare@gs1uk.org
Phone number	Freephone 0808 178 8799 or 020 7092 3501 (available Mon-Fri 9am-5pm)

11.2 Useful Resources

GS1 UK – www.gs1uk.org

Visit the GS1 UK webpage to access further information and support on GS1 Standards, including training resources available to GS1 UK members, as well as key member and industry events and news.

GS1 UK's Healthcare Portal – <https://healthcare.gs1uk.org>

Head to GS1 UK's Healthcare Portal to see how GS1's global standards for unique identification and AIDC technologies are used within the Healthcare sector to improve patient safety and drive clinical and operational efficiencies.

GS1 Standards – <https://www.gs1.org/standards>

The GS1 Standards homepage is where users can access the most up-to-date releases of all GS1 Standards and Guidelines documentation and includes a wealth of resources on everything from GS1 Identification Keys to GS1 Data carriers, to sector and application specific guidance, showcasing Standards in Action.

NHS Digital: Standards and Collections – www.digital.nhs.uk

Access an alphabetical list of all published Data Alliance Partnership Board (DAPB) standards and collections. The list is updated on a monthly basis, following the approval of new items, and changes, by the DAPB.

12 Appendices

Appendix 1: My Numberbank

My Numberbank is the official GS1 UK database which enables members to assign Global Trade Item Numbers (GTINs) and product data in one place. My Numberbank enables the creation and management of other GS1 numbers, like Global Location Numbers (GLNs) and GTIN-14s for higher packaging hierarchies such as outer cases or cartons, with the following features and benefits:

- Find and allocate product identifiers to each of your products
 - Ensures you stay within your licensed GS1 UK Company Prefix capacity
 - Shows you how many GTINs or GLNs you have assigned and how many you have left
- Safe and secure product information, with data captured against each product identifier in a single place
 - Work more efficiently knowing your product data is automatically organised
 - Avoid creating and using multiple spreadsheets to manage your product information
 - Backs up your product data in a secure, password-protected online platform
- Real-time access for your product identifiers and data anytime, anywhere
 - Allows you to quickly upload and download data in .csv format which you can share with trading partners and online platforms
- Avoid mistakes and maintain the data integrity of your product identifiers and products online and offline
 - Easily create, manage, and share GTINs and GLNs. My Numberbank automatically incorporates your GS1 Company Prefix and calculates the entire GTIN/GLN for you
 - Be confident that GTINs and GLNs you create are properly formatted and follow GS1 standards

To start using MyNumberbank easily and quickly, please visit the [MyNumberbank Support](#) webpage.

Appendix 2: The GS1 Subset of International Standard ISO/IEC 646

This table lists all characters allowed for use in GS1 Application Identifier (AI) element strings. All other ISO/IEC 646 characters that are not listed here are not allowed in GS1 Application Identifier (AI) element strings.

Figure 31: GS1 AI encodable character set 82

Graphic symbol	Name	Coded representation	Graphic symbol	Name	Coded representation
!	Exclamation mark	2/1	M	Capital letter M	4/13
"	Quotation mark	2/2	N	Capital letter N	4/14
%	Percent sign	2/5	O	Capital letter O	4/15
&	Ampersand	2/6	P	Capital letter P	5/0
'	Apostrophe	2/7	Q	Capital letter Q	5/1
(Left parenthesis	2/8	R	Capital letter R	5/2
)	Right parenthesis	2/9	S	Capital letter S	5/3
*	Asterisk	2/10	T	Capital letter T	5/4
+	Plus sign	2/11	U	Capital letter U	5/5
,	Comma	2/12	V	Capital letter V	5/6
-	Hyphen/Minus	2/13	W	Capital letter W	5/7
.	Full stop	2/14	X	Capital letter X	5/8
/	Solidus	2/15	Y	Capital letter Y	5/9
0	Digit zero	3/0	Z	Capital letter Z	5/10
1	Digit one	3/1	_	Low line	5/15
2	Digit two	3/2	a	Small letter a	6/1
3	Digit three	3/3	b	Small letter b	6/2
4	Digit four	3/4	c	Small letter c	6/3
5	Digit five	3/5	d	Small letter d	6/4
6	Digit six	3/6	e	Small letter e	6/5
7	Digit seven	3/7	f	Small letter f	6/6
8	Digit eight	3/8	g	Small letter g	6/7
9	Digit nine	3/9	h	Small letter h	6/8
:	Colon	3/10	i	Small letter i	6/9
;	Semicolon	3/11	j	Small letter j	6/10
<	Less-than sign	3/12	k	Small letter k	6/11
=	Equals sign	3/13	l	Small letter l	6/12
>	Greater-than sign	3/14	m	Small letter m	6/13
?	Question mark	3/15	n	Small letter n	6/14
A	Capital letter A	4/1	o	Small letter o	6/15
B	Capital letter B	4/2	p	Small letter p	7/0
C	Capital letter C	4/3	q	Small letter q	7/1
D	Capital letter D	4/4	r	Small letter r	7/2
E	Capital letter E	4/5	s	Small letter s	7/3
F	Capital letter F	4/6	t	Small letter t	7/4
G	Capital letter G	4/7	u	Small letter u	7/5
H	Capital letter H	4/8	v	Small letter v	7/6
I	Capital letter I	4/9	w	Small letter w	7/7
J	Capital letter J	4/10	x	Small letter x	7/8
K	Capital letter K	4/11	y	Small letter y	7/9

Graphic symbol	Name	Coded representation	Graphic symbol	Name	Coded representation
L	Capital letter L	4/12	z	Small letter z	7/10

Appendix 3: Check Digit

The table below explains how the Modulo 10 check digit algorithm works. This algorithm is identical for all fixed length numeric GS1 data structures (including GDTI, GLN, GRAI etc.).

Figure 32: Check digit algorithm

Digit positions																			
GTIN-8												N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈
GTIN-12							N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂	
GTIN-13						N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂	N ₁₃	
GTIN-14					N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂	N ₁₃	N ₁₄	
17 digits		N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂	N ₁₃	N ₁₄	N ₁₅	N ₁₆	N ₁₇	
18 digits	N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂	N ₁₃	N ₁₄	N ₁₅	N ₁₆	N ₁₇	N ₁₈	
Multiply value of each position by																			
	x3	x1	x3	x1	x3	x1	x3	x1	x3	x1	x3	x1	x3	x1	x3	x1	x3		
Accumulated results = sum																			
Subtract sum from nearest equal or higher multiple of ten = check digit →																			

Figure 33: Check digit calculation example

Example of a check digit calculation for the 18-digit field																		
Positions	N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂	N ₁₃	N ₁₄	N ₁₅	N ₁₆	N ₁₇	N ₁₈
Number without check digit	3	7	6	1	0	4	2	5	0	0	2	1	2	3	4	5	6	
Step 1:	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
multiply by	3	1	3	1	3	1	3	1	3	1	3	1	3	1	3	1	3	
Step 2: add up results to sum	=	=	=	=	=	=	=	=	=	=	=	=	=	=	=	=	=	=
	9	7	18	1	0	4	6	5	0	0	6	1	6	3	12	5	18	=101
Step 3: Subtract sum from nearest equal or higher multiple of ten (110) = check digit (9)																		
Number with check digit	3	7	6	1	0	4	2	5	0	0	2	1	2	3	4	5	6	9

For quick checks or one-off calculations, a [GS1 online check digit calculator](#) is also available.

Appendix 4: Function 1 (FNC1) Symbol Character

The Function 1 symbol character (FNC1) is a non-printable, invisible character which serves two important purposes in the GS1 system.

Start character: FNC1 is used as a start character to differentiate a GS1 barcode, from a generalised non-GS1 barcode. When a barcode scanner detects a FNC1 character in the starting position of a GS1 barcode symbol, it transmits a symbology identifier to indicate the GS1 symbology type. This enables systems to interpret and process the encoded data according to GS1 Standards.

Separator character: FNC1 is also used as a separator character to indicate the end of a variable length element string, or an element string which has not been predefined in length.

The separator character MAY be FNC1 or the control character <GS> (ASCII value 29 (decimal), 1D (hexadecimal)). When either FNC1 or <GS> is used as a separator character, the scanner MUST transfer the character value as control character <GS>.

The FNC1 symbol character has the codeword 232 which is usually generated automatically when using software that is capable of producing GS1 compliant barcode symbols. However, it is worth noting that each software supplier MAY develop their own method of obtaining the correct encoding of special characters in the form of codeword 232.

Appendix 5: Element Strings with Predefined Length

The table below provides a list of the first two digits of the Application Identifiers (AI), which have been predefined in length, so that their end is determined.

These element strings do not require any FNC1 separator character. All other element strings, even if defined as fixed length, are not considered predefined length and MUST include a FNC1 separator character if followed by another element string.

Figure 34: Table of GS1 predefined length element strings

First two digits of the GS1 Application Identifier ⁸	Number of characters (GS1 Application Identifier and data field)
00	20
01	16
02	16
(03)	16
(04)	18
11	8
12	8
13	8
(14)	8
15	8
16	8
17	8
(18)	8
(19)	8
20	4
31	10
32	10
33	10
34	10
35	10
36	10
41	16

⁸ Numbers in parentheses are not yet assigned.

Appendix 6: Linear Barcode Orientation



Barcode orientation is important for linear symbols, especially with consideration of the print process and any curvature of the item where the barcode is required.

The preferred placement is picket fence orientation if the printing process and curvature allow. This is for a few reasons.

Firstly, all on-demand printers, whether thermal transfer, inkjet or laser, generally print crisper, more well-defined edges if they are printing linear barcodes in picket fence orientation. This is due to the bars going in the same direction as the substrate when it passes through the printer.

Secondly, print defects caused by issues with the print head are usually more visible, on picket fence oriented linear barcodes as they often appear as horizontal white lines. These types of defects can be more difficult to spot on barcodes printed in ladder orientation, as they can be mistaken as light bars on the symbol, meaning the data and barcode readability may be compromised.

Figure 35: "Picket fence" and "ladder" orientation explanation

Picket fence orientation	Ladder orientation
	
<p>Printing a barcode so that the bars are vertical to the base of the product.</p>	<p>Printing a barcode so that the bars are horizontal to the base of the product.</p>

Appendix 7: LocationManager

LocationManager holds Global Location Numbers (GLNs) for organisations in one central repository to provide a single source of truth for all location information across the sector.

Managing locations centrally in this way improves end-to-end product traceability enabling better value across the NHS, and safer care for patients.

It enables products to be tracked and traced seamlessly throughout the entire supply chain and patient care pathway. This facilitates inventory management and most importantly, improves product recall processes, to reduce the risk of harm to patients.

To ensure this become commonplace for products supplied into the NHS, NHS Trusts across the country have confirmed their commitment to the adoption of GLNs and the use of LocationManager.

Who should use LocationManager?

All key healthcare stakeholders involved in the manufacture, distribution, supply, purchase and use of healthcare products and equipment should be using LocationManager.

This includes:

- Suppliers
- Brand owners
- Manufacturers
- Distributors
- Wholesalers
- NHS arm's length bodies
- Regulatory authorities
- NHS Trusts

What can you do with LocationManager?

- Define and manage your own account and location information
- Add or create GLNs individually or through bulk upload
- Access and search for any GLN information you require 24/7
- Maintain and manage your users or direct contacts
- Subscribe to locations and receive real-time notifications as locations change within a given organisation