The Global Language of Business

GS1 UK compliance specification for the NHS

July 2020

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Contributors

Name	Organisation
Robert Flack	GS1 UK
Paul Reid	GS1 UK

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GS1 UK has reviewed the content of this document thoroughly. All statements, technical information, recommendations, schedules and costs (where specified) are believed reliable, but the accuracy and completeness thereof are not guaranteed or warranted unless otherwise stated.

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Introduction

> "Our technology landscape is very heterogeneous, and interoperability is poor. This increases costs because we are not taking advantage of economies of scale, increases errors and introduces delays in the transmission of data from one system to another, which in turn has patient safety implications, and delays the digitisation of those parts of the system still very poorly served by technology".
>
> *The Rt Hon Matt Hancock MP, Secretary of State for Health and Social Care*

For almost 20 years the NHS has been advocating the use of GS1 standards as the coding of choice for new applications with that adoption becoming mandated through the NHS eProcurement Strategy published in May 2014. GS1 standards should be considered as the primary open global standard for relevant data elements and barcodes, particularly where Auto-Identification and Data Capture (AIDC) is required.

In line with current drives to improve the consistency, flexibility and interoperability of technology across health and social care all systems developed in-house, commissioned, procured or adopted should be "GS1 compliant" (as applicable). This buyers guide aims to provide guidance for buyers and commissioners on what that really means and how to ensure that new systems are GS1 compliant.

What does "GS1 compliant" mean?

GS1 standards have provided a common foundation for business and healthcare for over 40 years, covering a range of areas including:

- Identify – globally unique identification keys
- Capture – machine readable representation of data
- Share – exchange of business-critical information.

These open standards are now used consistently in over 150 countries with compliant codes now being read over five billion times a day in healthcare, retail and logistics operations globally.

Identify

Across healthcare GS1 Identification (ID) Keys are being used to consistently and uniquely identify various data elements including (but not limited to) patients, staff, products, places, procedures, documents, records, equipment and transport containers. Using Electronic Patient Record (EPR) systems as an example, if the system has the capability to store or use any of the elements detailed in the table below, the appropriate GS1 Key should be used as either a primary or secondary identifier. .

Example: *GS1 ID Keys required for EPR systems*

Element	GS1 ID Key		Element	GS1 ID Key
Patient	GSRN and SRIN *		Care giver or staff	GSRN and SRIN
Location	GLN *		Equipment	GIAI
Product	GTIN *		Record or document	GDTI

Note: The keys identified with an * are the core enablers and considered to be the most essential to EPR systems.

Note: Other data elements are available and can easily be identified using GS1 ID keys however the ones listed in the table above are considered as most applicable to an EPR system.

Note: In some specific cases alternative standards have been agreed for particular data elements, such as the use of International Society for Blood Transfusion (ISBT) for blood management items.

"GS1 compliant" shows that the reviewed system utilises the correct GS1 ID keys as a primary or secondary identifier for the required data elements based on the functionality and purpose of the system being considered.

Capture

A key benefit of adopting GS1 standards is the ability to represent the different ID keys in machine readable formats including barcodes, data matrices and RFID tags. There are a variety of printed 'barcodes' available as illustrated below with GS1 standards specifying the format and structure of these representations. Using the patient identity bands as an example, systems which produce the bands should ensure that the data matrixes and human readable information is in line with the requisite standards to ensure consistent and accurate reading by other systems. Further details of the technical requirements of these standards are available from GS1 UK.

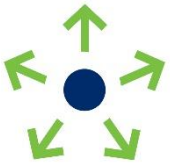
Example: *GS1 barcode formats*

Note: It is recommended that new systems be capable of utilising, including printing and reading, GS1 DataMatrix two dimensional barcodes as these can hold a significant amount of information and may remain legible even when printed at a small size or etched on products.

Note: RFID tags can also be used to store GS1 ID keys and are effective where the relevant equipment for reading the codes is available.

"GS1 compliant" shows that the reviewed system utilises the requisite GS1 standards in the printing, production and reading of barcode labels and RFID tags.

Share



Commonly identifying key data elements across various systems supports data sharing and transparency however this also requires use of common and consistent approaches. Government Digital Services (GDS) sets out standards for APIs and codes of practice in their Service-Toolkit.

For product and place information, where structured data is used across multiple organisations and for which an approach of 'create once and use often' should be followed GS1 have established specific data registries that can be equally accessed by multiple organisations.

These include:

- **Global Data Synchronisation Network** (GDSN) – a set of global data pools built in compliance with GS1 standards (the Global Data Dictionary) and used by manufacturers and distributors to share product data consistently with customers. Where required, systems (such as Catalogue Management Systems) should be capable of accessing product master data direct from a GS1 GDSN compliant data pool.

- **LocationManager** – a central repository for location information across health care, social care and supplier organisations. Where required, systems (such as Purchase-to-Pay) should be capable of accessing location data direct from LocationManager.

NHS organisations and suppliers are also adopting **PEPPOL**[1] as the standard approach for transmitting documentation and information with suppliers, including documents such as purchase orders, invoices and advanced shipping notices.

"GS1 compliant" shows that the reviewed system uses the relevant standards for data exchange and is able to access the appropriate national data sources, depending on the requirements.

Demonstrating "GS1 compliance"

Example: *GS1 UK approved product certificate*

GS1 UK approved product certificate

GS1 Approved

This is to certify that the product detailed below has been assessed by GS1 UK and has been found to be capable of supporting applicable GS1 standards.

Product:

Version:

Date approved:

This certificate is valid for three years from the date approved.

GS1 UK
Hasilwood House
60 Bishopsgate
London
EC2N 4AW
T +44 (0)20 7092 3501
E support@gs1uk.org
www.gs1uk.org

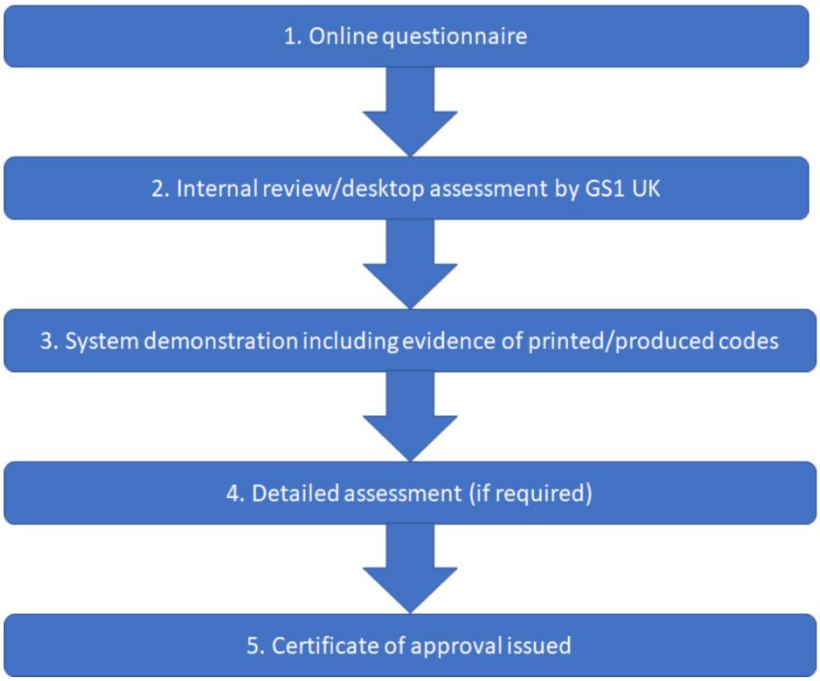
Member support team (Freephone)
+44 (0)808 178 8799

Paul Reid
Head of standards and consulting
GS1 UK

[1] PEPPOL stands for Pan-European Public Procurement Online

GS1 UK has developed a comprehensive approach, available to all system providers, whereby it will review and assess an individual system release's use of the required GS1 standards and adherence to the specifics of those standards. The successful outcome of the process will be the award of a certificate stating "GS1 UK approved product".

GS1 UK approved product certification process



Note: The assessment process, and resulting certificate, relates to only to that particular version, module or release of a provider's system and is specific for the system's primary purpose(s). Both the tested version or release and the primary purpose(s) will be clearly stated on the issued certificate of approval. When a new (major) system release is made available providers will be required to have the new release re-assessed and obtain a corresponding updated certificate of approval from GS1 UK.

Requesting a system review and issuing of a certificate of approval for a specific module or release of software is a chargeable service and is available to all GS1 members. Further information can be found at www.gs1uk.org

GS1 UK also operates a Partner Programme providing further guidance, support and engagement for Partners including ongoing review, assessment and approval of systems.

Provision of a valid certificate of approval should be considered sufficient evidence that the proposed system version, module or release has been reviewed and assessed as GS1 compliant as required for systems performing that desired purpose(s).

Note: While the preferred situation is for a proposed system version, release or module to have a corresponding certificate of approval at the point of tender response or project initiation that may not always be possible as technology evolves, and systems are developed. As an absolute minimum it is expected that commitment be given at point of tender response or project initiation that a review is being sought and that provision of a valid certificate of approval will be made a contractual or project obligation prior to a system being commissioned for use. This applies equally for systems procured and those developed in-house.

Wording in requirements documents

Question to be used in specifications and tenders for new systems

Proposed systems must be compliant in their use of specific GS1 standards as they relate to {*primary system purpose(s)*} systems. Evidence that a system is GS1 compliant shall be provided in the form of a GS1 UK approved product certificate for the specific system version and module being proposed.

In support of the NHS Code of conduct for data-driven health and care technologies, NHS digital, data and technology standards, Government Digital Services Technology Code of Practice and the NHS eProcurement Strategy, systems developed or adopted by healthcare organisations should be GS1 compliant. Adoption of the standards also supports adherence to the requirements of Medical and Invitro Diagnostic device regulations (MDR and IVDR) as well as Falsified Medicines Directive (FMD) in the verification and tracking of Unique Device Identification (UDI). This is in line with the Medicines and Medical Devices Bill 2019/21 (https://services.parliament.uk/bills/2019-21/medicinesandmedicaldevices.html). The question shown above in bold should be included in system specifications and tenders as a mandatory pass or fail question.

The specifics requirements to be considered GS1 compliant will differ depending on the primary nature or purpose of systems being purchase or commissioned. This purpose should be specified, recognising that a single system can deliver more than one primary purpose, selecting for the list below. The list will continue to develop as the use of GS1 standards expands across Health and Social Care. An up to date listing including further information on the specific definitions and requirements of each can be found by contacting jill.carver@gs1uk.org.

System primary purpose listing

Clinical	Purchase and supply
Electronic Patient Record (EPR)	Enterprise Resource Planning (ERP)
Patient Administration System (PAS)	Purchase to Pay (P2P)
Patient Level Information and Costing System (PLICS)	Inventory Management Systems (IMS)
Pharmacy Management System (PMS)	Catalogue Management System
Patient Medication Record (PMR)	Electronic Pharmacy Stock Management Systems
Electronic Prescribing and Medicines Administration (ePMA)	
Medicines Management	**Business management**
Theatre Management System	Finance Management System
Laboratory Information Management System (LIMS)	Human Resource Management Systems
Picture Archiving and Communication System (PACS)	Facilities Management System
Breast Milk Tracking Systems	

If the primary purpose of the system(s) being purchased or commissions is not shown, contact colleagues at GS1 UK who will be able to provide further guidance.

Sources of information

GS1 UK

Document	Website
ID Keys Details of the full range of GS1 Identification Keys including specification and guidance on allocation and management	https://www.gs1uk.org/support/our-standards/standards-library/id-keys
Barcodes Details on the standards and specifications of all acceptable forms of printed barcodes	https://www.gs1.org/standards/barcodes
GDSN Details of how the Global Data Synchronisation Network operates, the standards and a detailed listing of certified data pool providers	https://www.gs1uk.org/support/our-standards/standards-library/gdsn
LocationManager Further detail of GS1UK LocationManager – the UK's single national GLN registry including further detail on the use, allocation and management of GLNs	https://www.gs1uk.org/our-industries/healthcare/location-management/locationmanager
Support and training Further detail on specific standards, How To guides and on-line training	https://www.gs1uk.org/support-and-training
Member support team The team are available Monday to Friday from 9:00am to 5:00pm by phone and email	https://www.gs1uk.org/about-us/contact-us
Partner programme Further details on the GS1UK Partner Programme including a searchable listing of current Partners	https://www.gs1uk.org/our-partners
The systems standards lookup The document details the GS1 standards required in core systems used across the NHS. The categories shown cover the majority of clinical and administrative systems used.	See pages 10 and 11 below

NHSX and NHS Digital

Document	Website
NHS digital, data and technology standards framework	https://digital.nhs.uk/about-nhs-digital/our-work/nhs-digital-data-and-technology-standards/framework
Code of conduct for data-driven health and care technology	https://www.gov.uk/government/publications/code-of-conduct-for-data-driven-health-and-care-technology/initial-code-of-conduct-for-data-driven-health-and-care-technology
NHS eProcurement Strategy	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/344574/NHS_eProcurement_Strategy.pdf
Scan4Safety	https://www.scan4safety.nhs.uk/
Dictionary of medicines and devices (dm+d)	https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/dictionary-medicines-and-devices-dmd

Government Digital Services

Document	Website
Service Toolkit Government standards for the design, build and running of services	https://www.gov.uk/service-toolkit

PEPPOL*

Document	Website
What is PEPPOL?	https://peppol.eu/what-is-peppol/

MHRA

Document	Website
Medical Device Regulation (MDR) and In Vitro Diagnostic medical devices (IVDR)	https://www.gov.uk/guidance/medical-devices-eu-regulations-for-mdr-and-ivdr
Unique Device Identification (UDI)	https://ec.europa.eu/docsroom/documents/36664/attachments/1/translations/en/renditions/native
Falsified Medicines Directive (FMD)	https://www.gov.uk/guidance/implementing-the-falsified-medicines-directive-safety-features

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System standards lookup table

✓	Consider
✓	Required

System or Activity		Inventory Management Systems	Electronic Patient Records	Health and Care Records	ICT Infrastructure	Informatics, analytics & digital tools	Transformation & Change	Patient empowerment & activation	Demand management & capacity planning	Systems assurance support	Medicines optimisation	Purchase to Pay
Common abreviation		IMS	EPR									P2P
HSSF Lot			1	2	3	4 & 5	6	7	8	9	10	

Identifier	Primary GS1 Key	Secondary GS1 Key											
Patient	GSRN	SRIN			✓	✓		✓		✓	✓		✓	
Staff	GSRN	SRIN		✓	✓	✓		✓			✓		✓	✓
Place	GLN	extension		✓	✓	✓	✓	✓		✓	✓		✓	✓
Product	GTIN	GMN		✓	✓	✓		✓		✓			✓	✓
Equipment	GIAI				✓	✓		✓		✓	✓			
Record	GDTI				✓	✓		✓		✓			✓	
Document	GDTI				✓	✓		✓						
Procedure	GTIN	OPCS / ICD10 / SNOMED			✓	✓				✓				
Logistics & Shipping unit	GIAI	GRAI		✓										
Shipment / delivery	SSCC			✓										✓
GLN Registry interface				✓										✓
GDSN interface				✓										✓
Barcode standards (printed)				✓	✓	✓				✓	✓		✓	
Data Matrix Standards (printed)				✓	✓	✓				✓	✓		✓	
RFID standards (used)				✓	✓	✓				✓	✓		✓	
Barcode standards (read)				✓	✓	✓				✓	✓		✓	
Data Matrix Standards (read)				✓	✓	✓				✓	✓		✓	
RFID standards (read)				✓	✓	✓				✓	✓		✓	
PEPPOL				✓										

✓	Consider
✓	Required

System or Activity	Laboratory Information Management Systems	Finance Management Systems	Enterprise Resource Planning	Catalogue Management Systems	Theatre Management & Scheduling	Pharmacy Management Systems (stock)	Pharmacy Management System (dispensing)	Facilities Management System	Asset & Equipment Management System	Sterile Services	(Physical) Document Management System
Common abreviation	LIMS	FMS	ERP	CMS		PMS					
HSSF Lot											
Identifier	**Primary GS1 Key**	**Secondary GS1 Key**									
Patient	GSRN	SRIN	✓		✓		✓	✓	✓				✓
Staff	GSRN	SRIN	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓
Place	GLN	extension	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓
Product	GTIN	GMN		✓	✓	✓	✓	✓	✓		✓	✓	
Equipment	GIAI		✓	✓	✓		✓			✓	✓	✓	
Record	GDTI		✓		✓		✓		✓				✓
Document	GDTI		✓		✓							✓	✓
Procedure	GTIN	OPCS / ICD10 / SNOMED	✓		✓		✓					✓	
Logistics & Shipping unit	GIAI	GRAI	✓		✓							✓	
Shipment / delivery	SSCC		✓		✓								
GLN Registry interface				✓	✓					✓			
GDSN interface					✓	✓		✓					
Barcode standards (printed)			✓		✓		✓	✓		✓	✓		✓
Data Matrix Standards (printed)			✓		✓		✓	✓		✓	✓		✓
RFID standards (used)			✓		✓		✓	✓		✓	✓		✓
Barcode standards (read)			✓		✓		✓	✓		✓	✓		✓
Data Matrix Standards (read)			✓		✓		✓	✓		✓	✓		✓
RFID standards (read)			✓		✓		✓	✓		✓	✓		✓
PEPPOL				✓				✓					