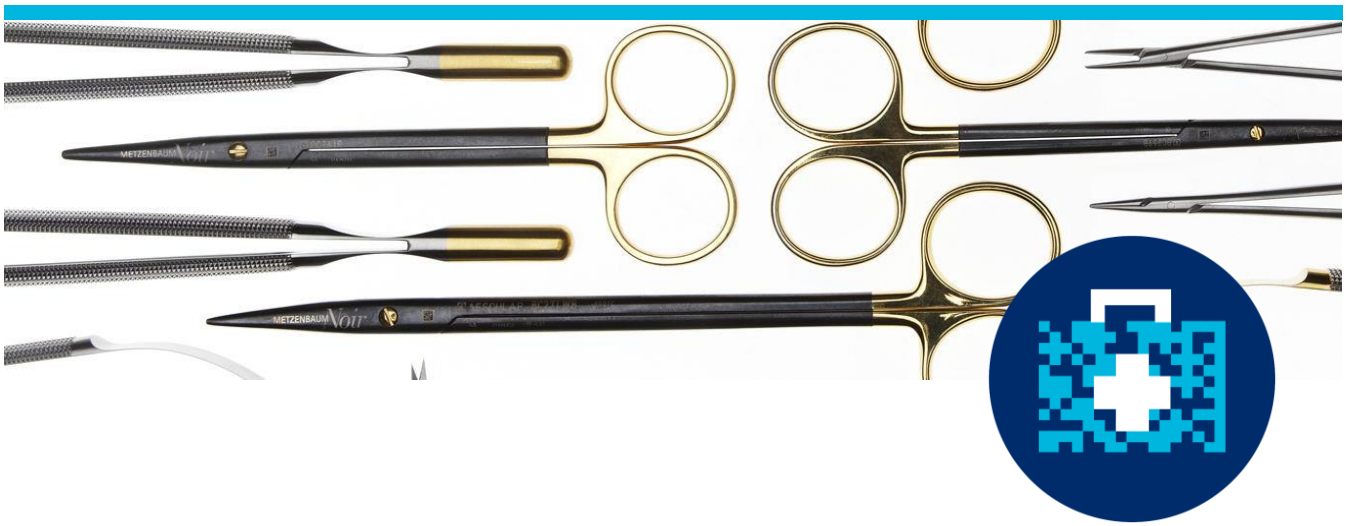
GS1 standards

Explanation for suppliers to comply with the requirements of the Dutch Implant Registry (LIR)

Release 1.0, Ratified, December 2017



Document Summary

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Disclaimer

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Introduction

GS1 barcodes and GS1 Data Source Healthcare help manufacturers comply with the requirements of the Dutch Implant Registry (LIR). This document contains the requisite information.

To maximise client safety, it must be possible to trace implants quickly and efficiently. For this purpose, the Minister of Health, Welfare and Sport has decided to establish a Dutch Implant Registry (*Landelijk Implantatenregister*, LIR). The LIR will be enshrined in legislation through an amendment to the 'Healthcare Quality, Complaints and Disputes Act' (WKKGZ). The goal is to safeguard the traceability of implants, right up to the client. The proposed legislative amendment contains a number of new obligations for healthcare providers and caregivers.

The consequence of the new obligations is that manufacturers are required to furnish medical implants with a Unique Device Identification (UDI) and to make the corresponding product data available to the LIR. Healthcare institutions are obliged to enter data about the inserted implants into Electronic Health Records and to supply data on their clients' implants to the LIR. You can find further details about this on *our website*.

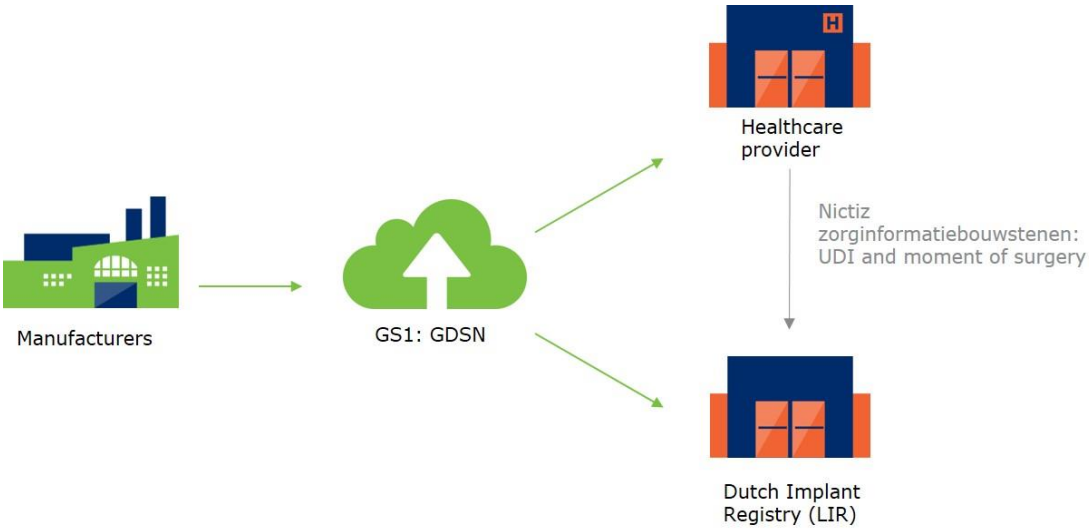

Figure 1.1: delivering product data

Contact and support

We offer our customers support and guidance in the use of barcoding and in the exchange of product data. For more information or to make an appointment for a free introductory meeting, please send an email to *healthcare@gs1.nl* or call the healthcare team at +31 (0) 20 5113820.

Our customer support department is always at your service. Send an email to *info@gs1.nl* or call +31 (0) 20 5113888.

1 Coding trade items

You can use GS1 barcodes to furnish medical devices with a Unique Device Identification (UDI). This is compliant with LIR requirements, as well as with other agreements and items of national and international legislation.

1.1 Order a code package

Order a GS1 code package from GS1 Netherlands. When you purchase a code package, you will receive a set of number sequences that you can use to uniquely identify products.

1.2 Assign UDIs

The UDI (Unique Device Identification) is a unique code consisting of a Device Identifier (DI) and a Production Identifier (PI). The DI is specific to the product in question, while the PI contains production information, such as the batch number/lot number, serial number, production date and expiration date. The exact data contained in the PI depends on the product in question, and on the risk class into which it is classified. You are responsible for adding information to the PI and for determining what type of information this should be.

You assign a UDI to each version or model of the medical device in question. A UDI contains:

- A unique *GTIN*

Plus, additional information such as:

- The batch number/lot number
- The serial number
- The expiration date (*NB: the LIR neither requires nor registers medical device expiration dates. Other national and international legislation/agreements may well require this data.)*

The GS1 standard uses *Application Identifiers (AIs)* to indicate the various items of information:

UDI	GS1 standards
DI Device Identifier	**GTIN/GS1 artikelcode** Global Trade Item Number
PI Production Identifier (PI) (if applicable) *The data may vary per manufacturing procedure and medical device.*	**AI** Application Identifier (AI): - Expiry date AI(17) - Batch/lot number AI(10) - Serial number AI(21)
DI+PI=UDI	**GTIN of GTIN + AI('s) = UDI**

Fig. 1.2: GS1 standards and UDI

1.3 Choose a symbol

Imprint the label with a UDI, in the form of HRI (Human Readable Interpretation format) *and* as a symbol. The healthcare sector uses two types of bar code – the GS1-128 and the GS1 DataMatrix. The market prefers the GS1 DataMatrix. In this compact two-dimensional code additional information can be included using Application Identifiers, without increasing the size of the symbol.

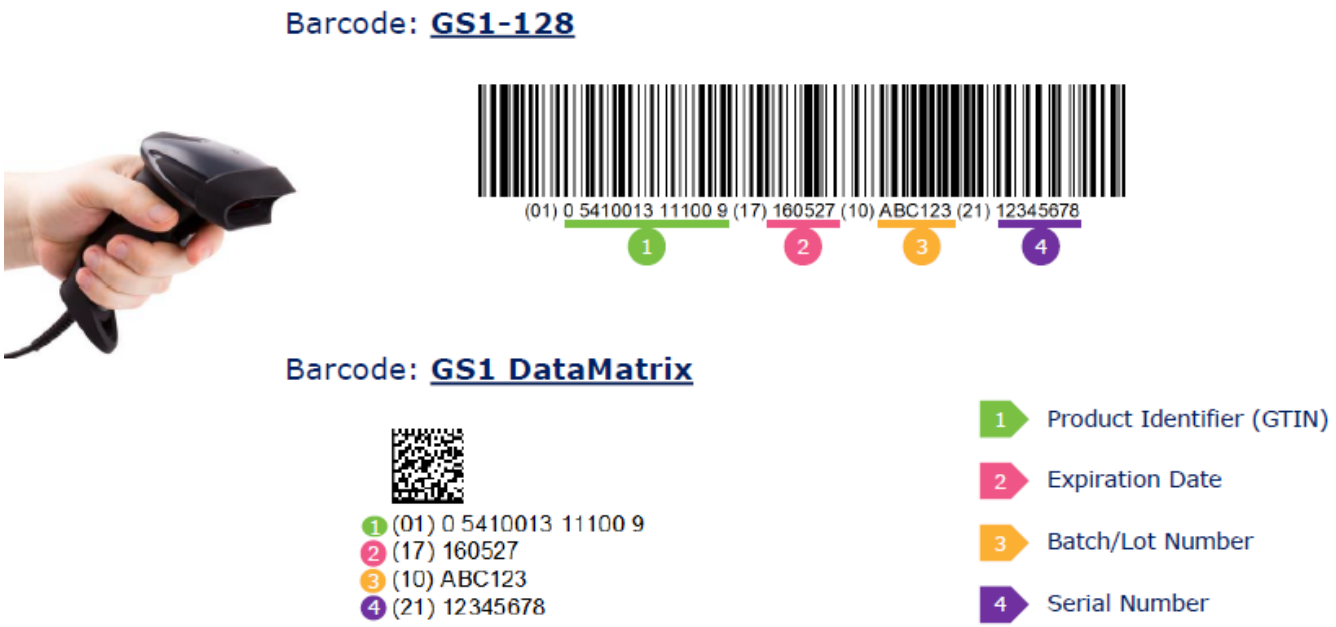

Figure 1.3: GS1 DataMatrix and GS1-128

2 Exchanging data

GS1 Netherlands provides a single central source for the exchange of item data in the healthcare sector: *GS1 Data Source Healthcare*. This solution gives everyone access to uniform, reliable item data, via a single central source. For this purpose, GS1 uses the worldwide GDSN standard (Global Data Synchronisation Network). Via *GS1 Data Source Healthcare*, you enter product data and publish these to national and international partners, including healthcare institutions and the LIR.

Both manufacturers and healthcare institutions have signed the *Agreements on the Uniform Coding of Medical Devices (ADC)*. According to the agreements, the stakeholders exchange product data via GS1 Data Source Healthcare. The Minister of Health, Welfare and Sport also has decided to link the LIR to the GDSN network.

2.1 Registering with GS1 Data Source Healthcare

Before you register for GS1 Data Source Healthcare, you must first order a code package. Use one of the codes in the code package as a GS1 address code (GLN), to identify your organisation. You assign this code to an internal location (for example, a central warehouse) or an external location (for example, at different branches).

You then register for GS1 Data Source Healthcare, using the *form* on our website. When you register for GS1 Data Source Healthcare, we will ask you for your GS1 address code (GLN). After submitting the form, you will receive a confirmation. Once the invoice has been paid, you will receive your log-in data.

2.2 Entering and publishing data

Once you have received your log-in data, we will contact you to schedule a webinar. During this webinar, we will help you prepare for the process of entering your item data. At the same time, you will find out how to enter item data and how to publish them for data recipients. A *web interface manual* is available on our website. You can refer to this for guidance when entering item data.

Using GS1 Data Source Healthcare, you can make your medical devices' product data available to healthcare institutions and to the Dutch Implant Registry (GLN: 8718734080008). Make sure to share your GLN with the Dutch Implant Registry, they need this to create a subscription and receive your data. Send an email to *info.lir@minvws.nl*.

Your data are forwarded to recipients via GS1 Data Source Healthcare as push messages. You can also directly use GS1 Data Source Healthcare to comply with other agreements and with items of national and international legislation.

2.2.1 LIR trade item data

Compliance with LIR requirements requires that you publish the following item data, at the very least, to healthcare institutions and the LIR:

Field names	GDSN name
Unique manufacturer's number	Information Provider GLN
Name of manufacturer	Information Provider Name
Unique identification (UDI)	Trade Item Identification (GTIN)
Product name	Trade Item Description
Product type	Additional Trade Item Classification System Code (GMDN)
Indicator of batch number/lot number Y/N	Has Batch Number (J/N)
Indicator of serial number Y/N	Serial Number Location Code

Figure 2.1: LIR item data

In the *field list* you will find the specifications of the fields required by the LIR (see column 'L' in tab 'NL HC'), together with the specifications of the mandatory GDSN fields. In addition to the fields that are mandatory for

the LIR, you are required to fill in a number of fields according to the GDSN standard. Once the complete set has been entered, you can send messages to your recipients.

2.2.2 Total overview of all item data

Aside from the mandatory LIR data, many more item data are exchanged within the healthcare sector for other purposes. This may be in connection with other items of legislation, more efficient inventory management, measures to reduce administrative burdens, Joint Commission International (JCI) etc. In the *field list*, you will find details of the complete dataset that is exchanged within healthcare.