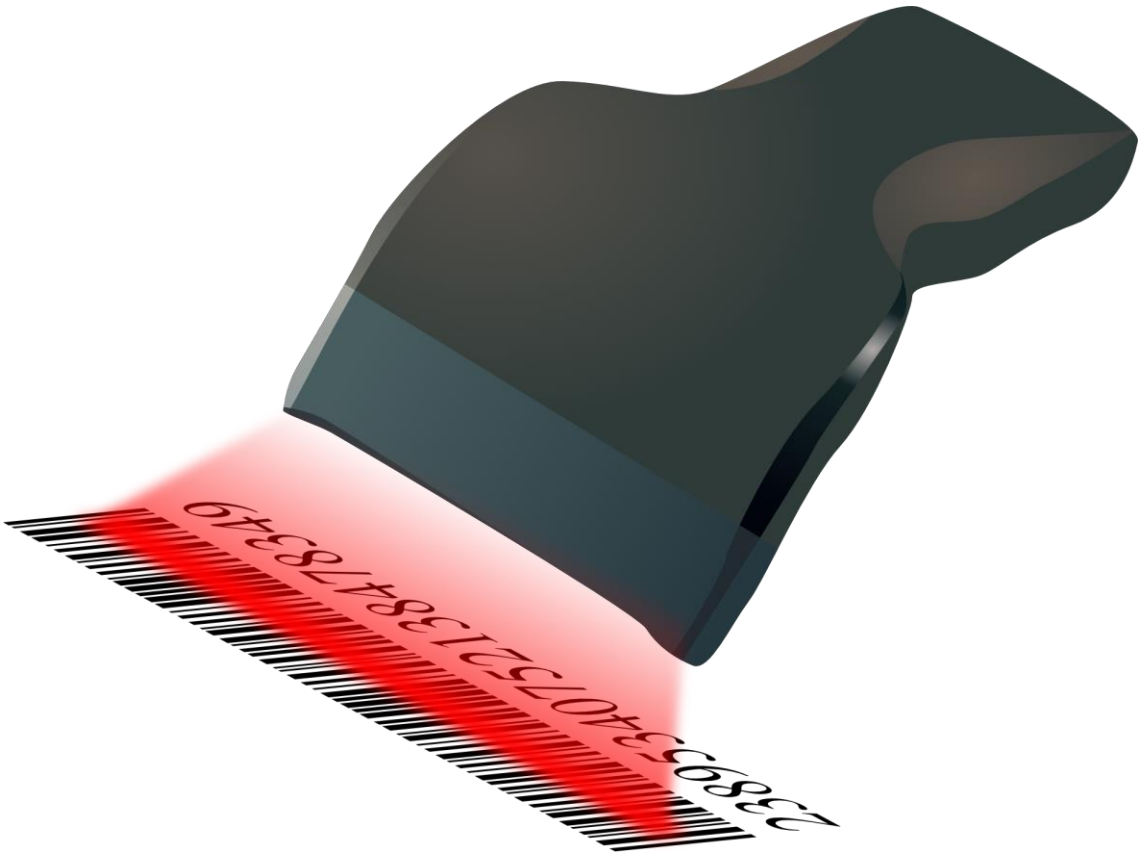
Agreements on unique coding medical devices
ADC



Inhoud

The agreements on unique coding medical devices have been established in a working group under the auspices of the Ministry of Health, Welfare and Sport. The parties concerned want to achieve that unique coding of medical devices will be implemented as soon as possible, but phased, in the Netherlands.

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Management summary

Background, goals and benefits

The unique coding of medical devices is good for patient safety and for efficiency. It is good for safety because, with electronic coding, it is always clear which medical device has been used for which patient. As a result, patients can be informed at an earlier stage, and the healthcare provider can take action more quickly, in the event of a recall, for example. It is good for efficiency because the entire supply chain has a more detailed knowledge of the inventory. As a result, the inventory can be better managed and controlled, which also means it can be smaller. In addition, a single scan and multiple use of the information has clear benefits, by linking up with other IT systems, for example, such as the Electronic Health Record (EHR) and the Enterprise Resource Planning (ERP) system. Furthermore, unique coding improves the coordination between suppliers and the hospital, which also leads to fewer errors and greater safety. And finally, uniform coding also supports existing registries, such as the implant registry and various quality registries.

The current situation has not reached this point yet. However, hospitals and medical device suppliers do ensure that only internationally accepted standards are used. In the Netherlands, that generally means GS1 or HIBCC. However, there are cases in which medical devices carry more than one code, because the supplier in question had to meet different requirements from different countries. As a result, it is often unclear which code should be scanned.

Environment and demarcation/scoping

On 5 May 2017, the EU announced new European legislation for medical devices. This is partly based on the United States' FDA UDI (Unique Device Identifier) legislation. In anticipation of the implementation of this Regulation, the Netherlands has already reached agreements with the healthcare profession concerning the rapid – but phased – introduction of unique coding. These agreements are entirely in keeping with the obligations imposed by Brussels. A working group directed by the Ministry of Health, Welfare and Sport identifies the agreements in question, the actions to be taken by suppliers and by hospitals, and the requisite changes to the software.

The agreements involve the list of implants covered by the bill relating to the National Implant Registry, which will come into force on 1 July 2018.

Approach

In order to keep the introduction of unique coding manageable, the initial phase was limited to hospitals. In future, however, such coding will be needed for all medical devices, regardless of where patients happen to be located. After all, the agreements are very much in line with a number of other programmes in the healthcare sector, such as 'Registration at source' and the National Implant Registry. The chosen approach is based on the chain, from the suppliers of raw materials to use in patients. By way of support, there is an implementation plan with a roadmap, practical examples, and tips for a phased introduction, as well as information on pitfalls and investments.

Agreements

Suppliers must mark medical devices with a UDI which, at the very least, must include a unique product number, a lot number, an expiration date and – optionally – a serial number. The UDIs on all packaging (primary, secondary, etc.) must be clearly and easily scannable, both in written form and in code

(linear barcode or datamatrix). Suppliers are required to check that this is, in fact, the case.

Suppliers must also ensure that there are as few codes as possible on the packaging, and that as much information as possible is included in a single barcode. In addition, agreements have been reached concerning the Central Article Database: suppliers will ensure that a standard data set relating to the medical devices in question is held at a central location. Pending the EU legislation, that location is the Dutch GS1 Data Source Healthcare solution.

Hospitals are responsible for agreements at different levels. They must ensure that there is a procedure for registering and tracing medical devices throughout the institution. The relevant departments are involved, and their employees are given suitable training. The uniform coding is embedded in the safety management system, and systems such as ERP, the Hospital Information System (HIS) and EHR can be linked in. This will involve a special focus on the IT systems associated with the various applications. In addition, links to quality registries and to the National Implant Registry can be added. Furthermore, a procedure for retrieving data from the central article database will be established. The Board of Directors is responsible for the implementation of the agreements.

The effective date for the introduction of uniform coding is 1 July 2018. The working group will meet again in September 2018, to add more items to the list.

1 Agreements concerning the introduction of unique coding for medical devices and drugs

1.1 Background

The need for an internationally accepted standard for the coding of medical devices should be self-evident. The absence of such a standard involves risks to the safety of patients and may lead to wastage. In the case of medical devices in particular, it appears that different codes are used interchangeably in the various stages between the manufacturer and the patient. This is inefficient, and a potential source of errors. The use of coding could provide a solution.[1]

The medical devices market is global, so suppliers sometimes use more than one standard system. Hospitals and suppliers in the Netherlands see to it that only internationally accepted standards are used.

Purpose of this document

This document focuses on the preconditions for the introduction and use of coding, based on the three accepted standards for medical devices[2]. The document sets out details of the agreements to be honoured by suppliers and hospitals. It also describes the modifications needed to enable software suppliers to effectively update software for the registration of medical devices and, in due course, drugs. The working group established under the auspices of the Ministry of Health, Welfare and Sport has identified the preconditions needed.

1.2 Dot on the horizon

In the interests of patient safety, all medical devices must carry an encoded unique product number, as prescribed in the European Medical Device Regulations (MDR)[3]**.** This unique product number can be supplemented by a lot number and/or serial number and expiry date, if so required by the use of the device in question. This concerns medical devices in risk classes III, IIb, IIa and I.

Standards

In 2012, partly in response to previous incidents involving medical devices, the European Commission adopted a new set of regulations and presented a package of interim measures in the context of a 'Joint Action Plan'. This resulted in new regulations for the market authorisation of medical devices and in vitro diagnostics. The expected timeline for implementation of those regulations' coding requirements is 2021 for class III, 2023 for class II and 2025 for class I. The Netherlands is giving priority to the introduction of coding. Indeed, it is already making collective agreements with the various parties involved. These agreements are fully in line with the requirements from Brussels. The basic principle is that an internationally adopted standard for coding should be used in the healthcare industry: HIBCC, ICCBBA or GS1.

[1] Letter to Parliament entitled 'Safety of medical devices' dd[1] 4 February 2015: file://vsrvfile/homes$/jvh/Downloads/kamerbrief-over-veiligheid-medische-hulpmiddelen%20(1).pdf

[2] At a later time, details of the preconditions for drugs will also be discussed.

[3] EU Medical Device Regulation

Registration at source
If all healthcare products carry an international standardised code, this will simplify the various registration processes used by hospitals: a single scan can automatically create an entry in the patient's record and in the relevant registries. Making the maximum use of product identification will help us move towards an improved system of information provision. This is in keeping with Registration at source[4].

Acceleration Programme for Information Exchange between Patients & Professionals (VIPP)
The role of the patient is changing, so healthcare providers will give patients access to their own data from 2020 onwards. For more information see Appendix 3.

National Implant Registry (LIR) The purpose of the LIR is to help protect the safety of clients with implants, by improving implant traceability. The LIR is also used to support the monitoring duties of the Health Care Inspectorate (IGZ), in the area of incidents involving medical devices[5].

Intramural and extramural
Optimum safety in the future requires that the registration of all medical devices be organised effectively, no matter where the patient is located: within a hospital building, in a nursing home, or elsewhere, such as in the patient's home.

1.3 Scope

The introduction of unique coding is a complex process. Accordingly, in the initial phase, the working group has decided to focus on hospitals. By the introduction of the MDR unique coding will also have to be introduced into extramural practice.

The greatest health risks
In the interests of a manageable and realistic introduction, the focus is on products that involve the greatest health risk to patients. To this end the medical devices working group uses the list of implants for which the law proposal with regard to the National Implant Register will be effective at its inception. A detailed description is set out in Section 2.2.

1.4 Purpose of unique coding

The agreements concerning the introduction of unique coding on medical devices are intended to enhance patient safety and to boost the efficiency of healthcare.

- ✓ Safer, because the use of unique coding means that it is always clear which medical device has been used for – or which drug has been administered to – which patient. This is possible because the code is registered right down to the level of the patient, in the patient's record.
- ✓ More efficient, because the use of unique coding means that medical devices are visible throughout the entire logistics chain, thus improving control and inventory management. Indeed, one business case suggests that this would make it feasible to reduce the inventory. In addition, the visibility of expiry dates would make it possible to cut wastage due to devices whose expiry date has passed. This will generate a substantial reduction of costs. In addition, the one-time scanning and registration of information, for multiple use, cuts

[4] Hospital programme aimed at the unique capture of healthcare information during the healthcare process, to make it available for multiple use. That data capture process involves healthcare information modules that have been developed based on international standards.
[5] Parliamentary Papers (34483)

registration costs. One example is the registration of implants for the national implant registry.

Safety and efficiency will also benefit if the introduction of unique coding improves coordination between suppliers and healthcare providers. This can also lead to improved coordination within hospitals, as it will simplify the exchange of information between different IT systems. In this way, information about an implant used in a patient that has been recorded in the electronic patient record (EPR) can also be used by management software (ERP) to manage the inventory. It could also be used to calculate the cost of devices used during surgery (DOT). This information is also suitable for registering an implant in the national implant registry or in a quality registry such as the Dutch Arthroplasty Register (LROI) or the Dutch Breast Implant Registry (DBIR). Accepted coding standards ensure that systems designed for different purposes and different applications can work together.

1.5 Areas of commonality

The introduction of internationally accepted standards of coding has areas of commonality with five other healthcare projects, which are strongly interlinked:

- The National Implant Register[6] based on a list of implants by an order in council ;
- V.I.P.P.; see attachment 3
- Registration at source[7];
- Safe use of medical technology in hospitals covenant[8];
- the Safety Management System (SMS topics, including the safe use of medical technology, patient identification, and high-risk medication)[9];
- preventing wastage in healthcare.

1.6 Preconditions

Around thirty Dutch hospitals are now either actively preparing to introduce code scanning for medical devices, or have already done so. Based on the experience they have gained, a number of preconditions for the successful introduction of unique coding have been drawn up:

- The Board of Directors' support is critical to the project's chances of success. In this connection, we would also refer to the code of governance[10];
- A phased approach is needed to ultimately achieve full implementation.
- IT systems in healthcare institutions must be adequately equipped to process codes that comply with international requirements;
- The 100% presence of standardised codes is required; that is to say, Standards that comply with set requirements throughout the world;
- The code on the product complies with one of the three international standards;
- Ideally, each product should only carry a single type of coding;
- The availability of a central article database, containing product data on medical devices. These include such details as the product name, a unique article number and the name of the supplier. The hospital can use this data in its healthcare and administrative processes. In this way, errors involving this

[6] http://www.rijksoverheid.nl/nieuws/2015/01/30/medisch-implantatenregister-van-start.html
[7] http://www.nfu.nl/thema/registratie-aan-de-bron/
[8] http://www.rijksoverheid.nl/documenten-en-publicaties/convenanten/2011/12/23/convenant-veilige-toepassing-van-medische-technologie-in-het-ziekenhuis.html
[9] http://www.vmszorg.nl/themas
[10] NFU code of governance
NVZ code of governance

product data can be avoided. Moreover, it is more effective if healthcare providers can obtain this data from a central database, rather than each individual healthcare provider having to get this information separately from their suppliers.

1.7 Implementation plan

An implementation plan for the introduction of unique coding has been included in this guidance as an appendix. This plan is based on the existing roadmap entitled 'GS1 – traceability in hospitals' which, in the form of a website, primarily focuses on the steps to be taken by healthcare providers to implement traceability. Suppliers can turn to the standardisation organisations for support with the introduction of (and for explanations concerning) unique coding.

1.8 Agreements on unique coding in the Netherlands

The agreements on unique coding contained in this document were formulated by a working group under the direction of the Ministry of Health, Welfare and Sport. The stakeholders favour the phased introduction of unique coding in the Netherlands (on the basis of internationally accepted standards) as soon as possible. After all, it has to be possible for medical devices to be traded throughout the world, without any barriers. With this we move well in advance of the implementation of the MDR. The medical devices working group was made up of: The Netherlands Federation of University Medical Centres (NFU) the Dutch Hospital Association (NVZ), Nefemed (Dutch Federation of manufacturers, importers and distributors of medical products), the Federation of Medical Specialists (FMS), NEVIZorg (a subdivision of the Dutch Association for Purchasing Management), Netherlands Independent Clinics (ZKN), FHI Medical Technology, and a number of experts from the GS1 'Traceability in care' focus group.

2 Medical devices

2.1 Introduction

A standardised code makes it possible to trace products throughout the entire logistics chain, right up to the point at which they are used in patients. This traceability is also important in terms of patient safety, as it makes clear which medical devices the patient in question is using. The electronic registration of product expiry dates can help to prevent wastage. In these agreements, we use the list of medical devices as will be defined in the law proposal with regard to the National Implant Register. Cf 2.2.

2.1.1 Current situation

In accordance with the Safe use of medical technology covenant, the hospital registers and identifies all medical devices (and any peripherals) on receipt.

At present, the majority of products stocked by the major suppliers of medical devices are furnished with a GS1 code or an HIBCC code. In addition, some products may bear more than one code, so it is unclear which code should be scanned. This may be due to the fact that the information is divided into more than one code. Alternatively, in order to meet requirements from different countries, the supplier may have used a range of different codes.

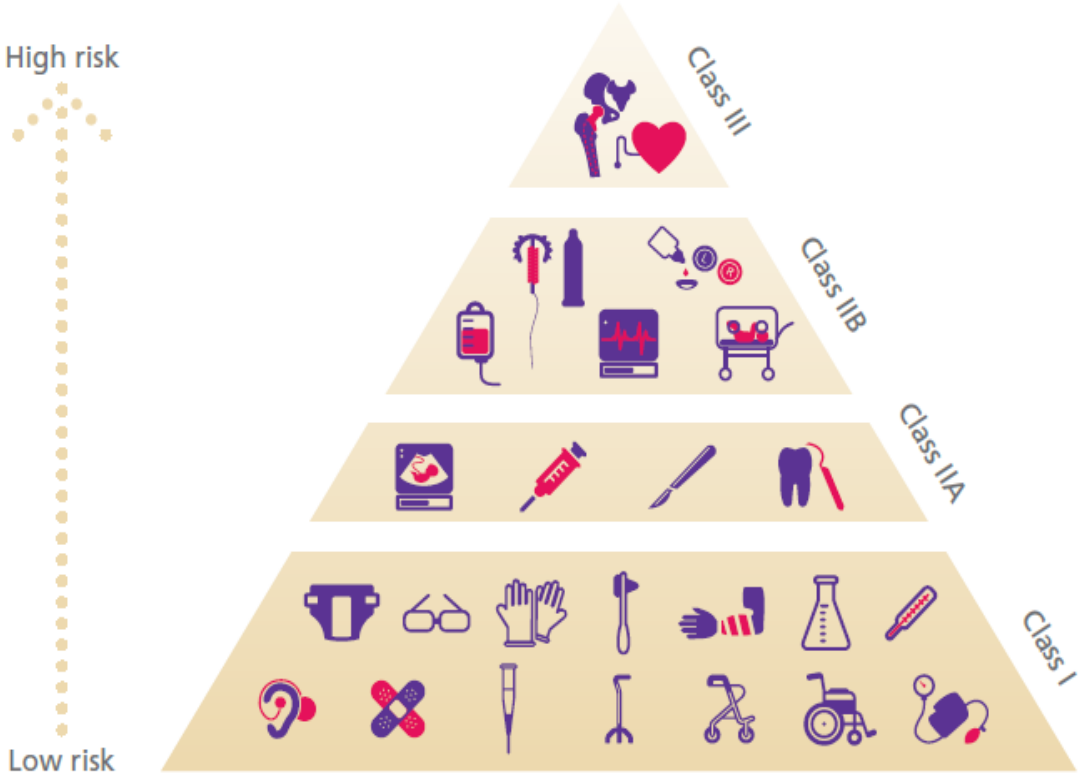
2.1.2 International context

At international level too, the need to improve the registration of medical devices is widely recognised. For instance, in September 2013, in the USA, the FDA put legislation into effect that makes it mandatory for all medical devices to carry a Unique Device Identifier (UDI). The introduction of this legislation will be phased by risk class. The UDI's must also be registered in an FDA Global UDI Database, together with a comprehensive set of data on the device in question[11]. On May 5th 2017, the European Union has declared the MDR Regulation, in which a UDI-system is introduced as well, which contains elements of the FDA UDI-legislation. The agreements forthcoming from the European regulation predominate the agreements in this document. In this document we have taken the European regulation as a starting point. The agreements in this document precede the implementation of the UDI.

2.2 Scope of medical devices

The term 'medical devices' covers many different products. They are classified by risk class: III, IIb, IIa and I.
Under the Healthcare Quality, Complaints and Disputes Act (WKKGZ), an order in council will determine which implants are to be covered by the bill relating to the National Implant Registry, when it enters into effect. We have based this document on the list to be included in this order in council. The list is included in this document as Appendix 4. In the case of those medical devices that meet these conditions, the unique coding must be imprinted on all packaging layers; i.e. up to and including the secondary *and* primary packaging. Following the entry into effect of the National Implant Registry bill on 1-7-2018, the coding for medical devices working group will meet again in September 2018 to discuss extending the list of implants.

[11] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm



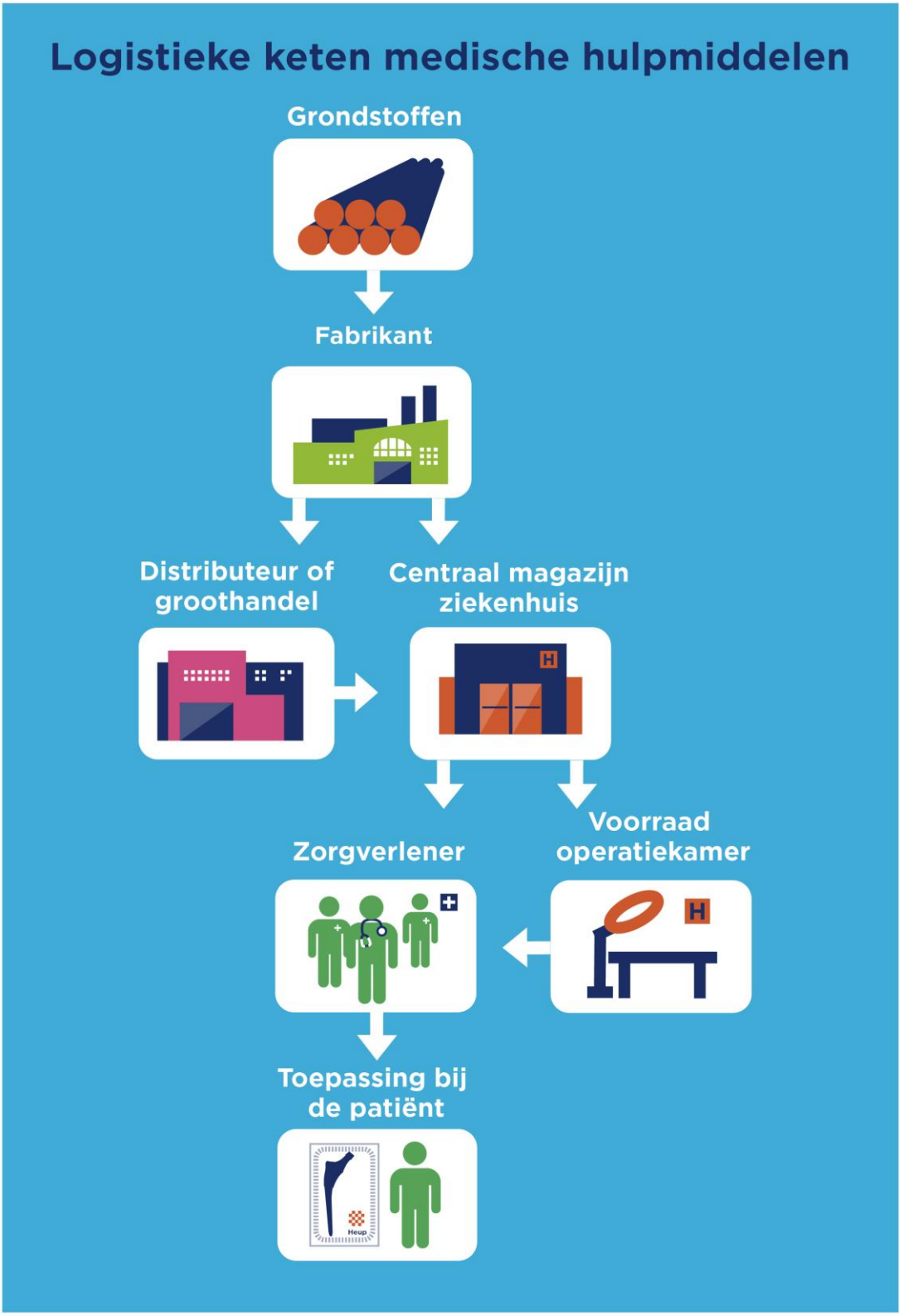
Bron: Eucomed

2.3 Chain-based approach

The agreements relate to the identification and traceability of medical devices throughout the entire logistics chain, from their production/delivery to their use in patients. Each medical device must be identifiable and traceable at every relevant point in time.

The logistics chain starts with the raw material supplier and ends at the hospital, with the patient. Hence, a range of hospital staff and departments are involved, such as procurement, logistics or facility services, surgical department, X-ray department, nursing ward, nursing staff, CCL, CSD, Medical Specialists, and the Board of Directors.

The figure below illustrates the points that a medical device passes through, within the logistics chain.



2.4 Implementation

A phased approach was applied to enable suppliers and healthcare providers to comply with the agreements within the prescribed period.

During the first phase, implementation will involve implants that appear in the list, as set out in Section 2.2. At the very least, suppliers must allocate a uniform barcode to each of the implants on this list before the end of the first phase. During this phase, these implants must also be scanned and linked to the patients in question by the healthcare provider.
Clearly, it is up to the healthcare provider to determine whether or not they wish to register other medical devices by means of barcode scanning. However, at the very least, they must be able to capture details of implants on the inclusion list in this way.

Following the implementation deadline of 1 July 2018, branch stakeholders will cooperate with the Ministry of Health, Welfare and Sport (VWS) in September 2018 to determine which medical devices should be added to the list.

Various tools are available to support the introduction of uniform bar-coding:

- Practical examples of hospitals
- Practical examples of suppliers

The standardisation organisations HIBCC and GS1 also offer support for implementation.

3 Information for suppliers and healthcare providers

3.1 Introduction of UDI in the Netherlands

Because the UDI is imprinted at the start of the logistics chain, and is then utilised by various parties in the chain until the device is finally used in patients, we will start with the agreements that are required for suppliers. We will then move on to the agreements required for hospitals to integrate UDIs into their healthcare and administrative processes.

3.2 Objectives

The purpose of agreements on unique coding for medical devices is to make the following improvements:

- Suppliers furnish their medical devices with a Unique Device Identifier (UDI), which makes it possible to trace these medical devices;
- Suppliers must see to it that medical devices are traceable from the moment of production until they are used in the hospital;
- Healthcare providers ensure traceability in the institution up until the moment that healthcare is actually administered to the patient in whom the device is to be used.

Results

The effects of the above agreements are:

- UDIs facilitate error-free data registration;
- In the event of a recall, it is easier to trace the location of specific products in the chain;
- The registration of medical device details is improving. This data is becoming more accessible to stakeholders, via a protected environment;
- By applying international standards to registration procedures, product identification can also take place outside the Netherlands. For instance, when a patient undergoes surgery abroad, the registration of any devices used can be easily shared with the hospital in the patient's home country;
- It becomes possible for hospitals to improve their inventory management.

3.2.1 Benefits for the National Implant Registry and for quality registries

In addition to the healthcare providers (see Figure 4.4), unique coding also supports existing registries. Given that the traceability of implants and of patients with such implants was inadequate, the Minister has decided to establish a National Implant Registry (see Section 1.2). Efforts are currently being made to establish a legal basis, to ensure that this registry is as reliable, complete, and effective as possible (see Parliamentary Papers 34483). The stakeholders, especially the healthcare providers, have indicated that the introduction of unique coding will simplify compliance with legal requirements. That's why they see this coding as a precondition for the implementation of the act.

In addition, unique coding supports the process of recording details of any medical devices used in the quality registries. It guarantees that the product code is unique, that all stakeholders are clear about the exact type of medical device concerned, and that they have details of its lot number or serial number. In this way, in the event of a recall, it is a simple matter to identify the healthcare provider and patient involved.

3.3 Introduction and regulation

We advise hospitals to use a phased approach to the introduction of these agreements. Together with this document, an implementation plan setting out the implementation timeline has been drawn up. The legal stipulations are leading, including the list which will be agreed on within the WKKGZ. While the Health Care Inspectorate (IGZ) endorses the importance of the agreement document.

The implementation of the European regulations for medical devices,in which the demand for unique identification has been taken up, has a starting date for registration from May 2020 onwardand for UDI coding from May 2021., with a phased introduction of the separate risk classes.

4 Agreements for suppliers

4.1 The framework

The packaging of a medical device must be furnished with a UDI. According to the FDA, this UDI can involve a standard identification system: HIBCC, ICCBBA or GS1.[12] The EU is expected to adopt this format, which also forms the starting point for this document.

In order to achieve a safe and workable system in hospitals, it is imperative that the UDI in question meets certain international wants and needs, such as the requirement that the UDI must uniquely identify the product type.

Codes have a variety of formats:

- The linear bar-code, or '1D code';
- The Data Matrix, or '2D code';

An example of a linear bar-code:

Two examples of a Data Matrix:

12 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIIssuingAgencies/default.htm

4.2 UDI: what does 'furnished with a code' mean?

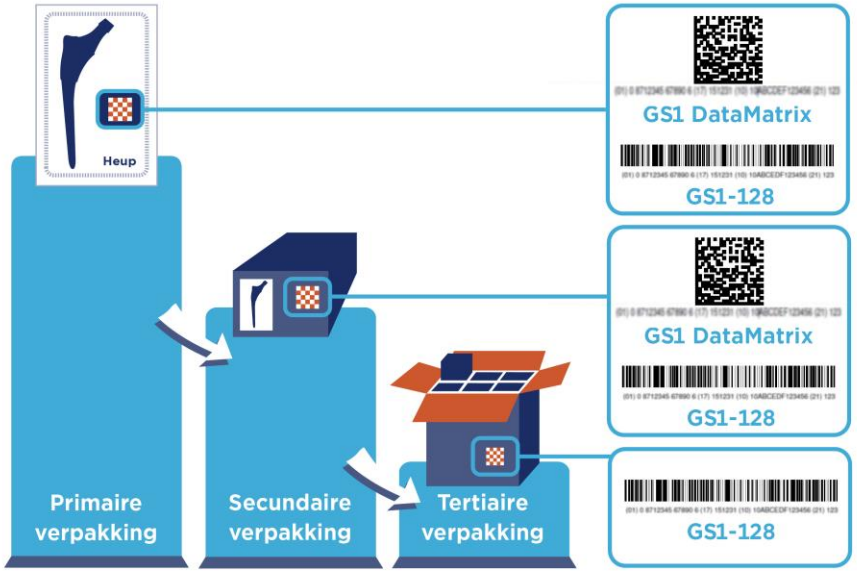
A UDI is a **unique** numeric or alphanumeric code consisting of a fixed component and a variable component:

- A Device Identifier (DI) – a mandatory fixed component that uniquely identifies the supplier and the device in question. We refer to this as the unique product number.

- A Production Identifier (PI) – a variable component of the UDI that is only added to the codes of products that involve a high degree of risk. The PI contains only data that is printed as script on the label:
  - ✓ Lot number
  - ✓ Expiry date
  - ✓ Serial number

Level coding

We take into account the different forms of product packaging (primary, secondary and tertiary) that may be encountered. The basic assumption is that it must be possible to track the product from the factory to the point at which it is used by (or implanted into) the patient.



Bar-coding per packaging level

A linear bar-code, a Data Matrix, or both, can be imprinted on the primary and secondary packaging. It is sufficient for the tertiary packaging to be imprinted with a linear bar-code. For an explanation of how bar-codes are imprinted, see: https://www.youtube.com/watch?v=bNI5MKGCTMs

Figure 1: Sample label with a UDI. The unique product number, lot number and expiry date are indicated on the label, both in script and in code:

Here, a linear code (bar-code) has been used, but a Data Matrix (which is more convenient in the case of small packages, for example) could also have been used.

Figure 2: the figure below applies to HIBCC.

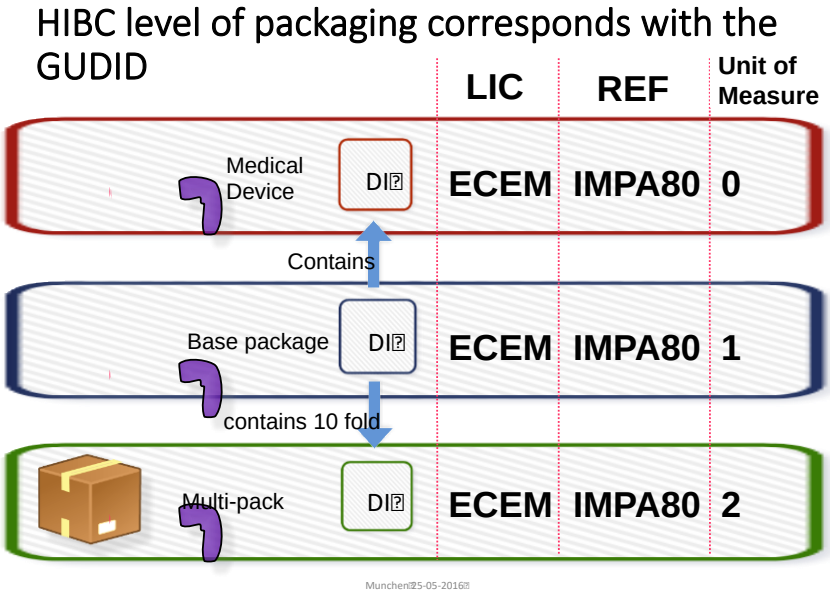


Figure 3: Example of a label with a UDI, on primary packaging. This is the final layer of packaging, which is in direct contact with the product itself. The unique product number, lot number and expiry date are indicated both in script and in a Data Matrix on the label:

4.3 Agreements on coding

1. The supplier ensures that the medical devices, as defined in Section 2.2, are furnished with a unique identification (UDI), to make them traceable.
2. The UDI has at least a Unique Product Number, a Lot Number, the Expiry Date and, optionally, a Serial Number. See also Section 4.2.
3. Each UDI must be present on the packaging both as script and as a bar-code.
4. The supplier – if they are not the manufacturer – verifies that the manufacturer has furnished the medical device with a UDI. If there is no bar-code, the supplier will ask the manufacturer to furnish the device with a bar-code, because the rule is 'coding is done at source'.
5. The supplier shall ensure that the code – as requested by Dutch healthcare providers – is clearly recognisable. See the above examples, in Figures 1 and 2: This is done by:
   a. Ensuring that the packaging is furnished with as few bar-codes as possible;
   b. Ensuring that, as far as possible, the information can be included in a single bar-code, rather than being spread over a number of different codes.
6. The supplier shall be responsible for ensuring that the bar-code is located at a suitable point on the packaging, to make it user-friendly for the purposes of scanning. To this end, the supplier shall use national and international agreements reached by standardisation organisations and governments.
7. The supplier shall ensure that the bar-code meets international specifications for bar-coding, such that the bar-code is always scannable.

For details of the internationally coordinated label requirements, we refer to the International Medical Device Regulators Forum (IMDRF) document entitled 'Guidance UDI - Unique Device Identification (UDI) of Medical Devices'.

4.4 Agreements regarding Central Article Data Exchange

The supplier shall be responsible for maintaining a standard medical device dataset which will be exchanged in a central way. Here, the unique product number or Device Identification (DI) is the link between the medical device itself and the data about this device. The data about the device is based on internationally accepted standards for article information. The fields involved are the same as those used in the FDA's current UDI database.
Until such time as details become available of the exact requirements to be imposed by the European UDI legislation on EUDAMED's EU UDI Database, a Dutch data source will be used.

As nothing is yet known about the data from the EU UDI Database, the decision has been taken to make a start in the Netherlands, using a limited dataset. This contains sufficient information to trace devices. The dataset required by the EU regulations is expected to be more extensive. It is expected that the data which will be exchanged will also feature in the EU UDI Database. The supplier's IT architecture must make allowance for a more extensive set of data. The exact nature of this data is not yet known. The US FDA Database (GUDID) currently requires suppliers to fill in 68 data fields.

GS1 Netherlands currently manages a tool by the name of GS1 Data Source. The GS1 Data Source contains the data needed to track the progress of a medical device through the entire logistics chain, from production to patient. It facilitates the use of both GS1 and HIBC product numbers:

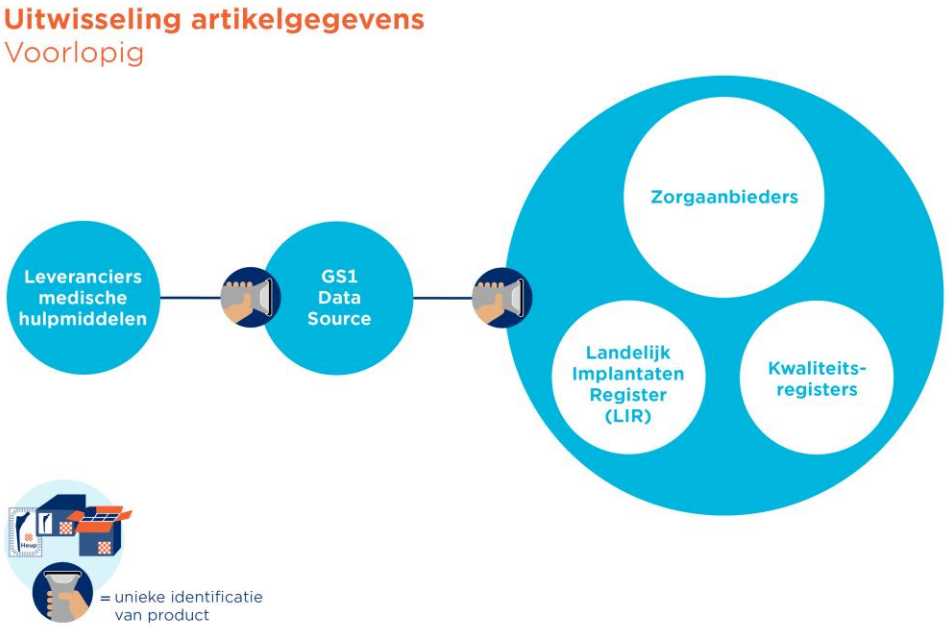
- ✓ Message number
- ✓ Supplier's name
- ✓ Unique supplier number
- ✓ Unique product number*
- ✓ Supplier's reference number
- ✓ Product name
- ✓ Packaging type (pallet, outer box, items etc.)
- ✓ Number in packaging
- ✓ Indicator Lot No. Y/N

* GS1- of HIBC-code

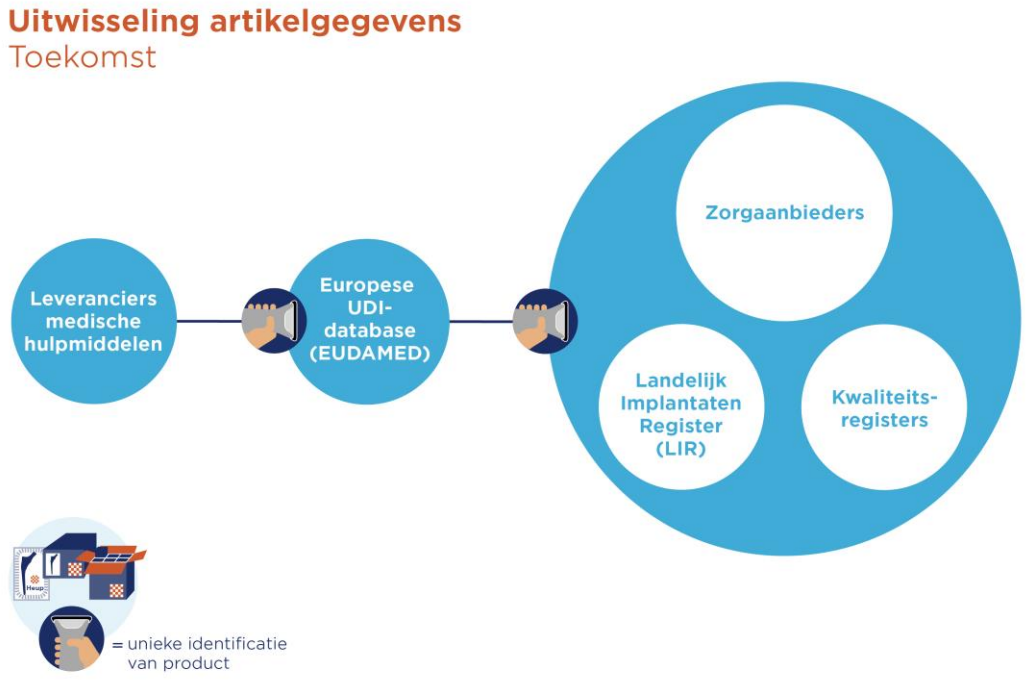
There are two ways of using the GS1 Datasource: complete or limited. The costs of use depend on a number of factors. More information can be found on:

https://www.gs1.nl/gezondheidszorg-0/gezondheidszorg/slag-gs1-data-source-healthcare. The complete version is based on the "Global Synchronisation Network"(GDSN). The limited version is a local, Dutch solution.

The figure below shows how the GS1 Data Source Healthcare can support healthcare stakeholders with the registration of a medical device.



In due course, when Eudamed has been supplied with the UDI-fields it will be possible for suppliers to upload article data via GS1 Data Source into Eudamed and for healthcareproviders to receive these data. or is in place, the Dutch data source will be replaced by the EU database. It is expected that EUDAMED will take on the task of managing this article database. The image below shows how article data will be exchanged in that situation:



4.5 Timeline

We use the following timeline for implementation:

Class	Furnished with a code and article data supplied on:
III and IIB implants on the list	1 July 2018

4.6 Transitional period

As from 1 July 2018 the products defined in Section 2.2 are allocated a UDI. In the intervening period, those products that have no UDI, which are on supply with the healthcare provider will be used first. The stakeholders involved have opted not to use temporary labels to avoid errors. Attaching the UDI is the responsibility of the supplier. Healthcare providers are advised not to change these labels.

Nefemed, FHI and FME will see to it that its members are informed.

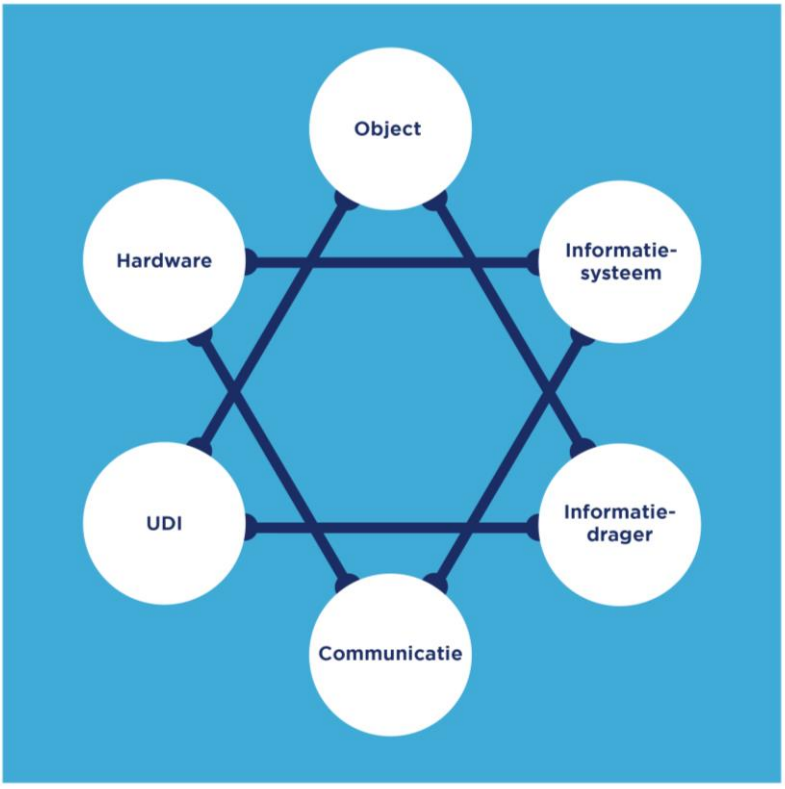
5 Agreements for healthcare providers

5.1 The framework

In connection with the European regulatory framework the UDI may be based on the standards of any of the following three accredited organisations: GS1, EHIBCC and ICCBBA. Healthcare providers have indicated that, in the interests of safety and efficiency, they have adopted the set of agreements in an effort to expand the use of an internationally accepted standard for identification and bar-coding. If the introduction of unique coding is to be successful, it is critically important to gain the support of the Board of Directors. They need to make sufficient funding available for the introduction.

With regard to unique coding, the following aspects are important for healthcare providers.

- The object: product, location, or person
- The information carrier: 1D, 2D, NFC
- The unique identification code: UDI
- The data processing system: EPR, ERP
- The hardware: device, scanner, smartphone
- Connection to the central article database
- The communication technology: wireless, 3G, Wi-Fi



In order to achieve a safe and workable system in healthcare institutions, it is imperative that the coding and UDI in question meet certain international wants and needs. We use the term "code" to refer to a range of formats:

- ✓ the linear bar-code, or '1D code';

- ✓ the Data Matrix or '2D code'[13];

Aside from the successful introduction of the coding in question, it is important for the hospital to be connected to the central Data Source article database. The unique product number is – after all – only a number. It conveys no details of the product name, for example. The supplier populates the article database with correct information about the device. The hospital uses this basic product data to register the device in its IT systems, along with details such as the correct name, the name of the supplier, and the packaging. For details of the dataset, see Section 5.4.

The product number (DI) can also be used as a reference when registering a medical device in the national implant registry and the quality registries. In this way, all of the parties involved are clear about the exact type of medical device concerned.

5.2 Start of coding: defining scope of project at healthcare provider

The introduction of UDI in hospitals is a complex process involving various departments, wards and IT systems. Also, a large and diverse range of medical devices is used in healthcare institutions.

1. When introducing a code, the all-important first step is to determine the scope involved. Which objects need to be identified in which process?
2. Have all of the objects to be identified been furnished with a UDI?
3. Have all of the objects to be identified been furnished with a code? To coordinate with the approach to risk taken by suppliers, it is best to start the registration process with medical devices in risk classes III and IIb.
4. The lessons learned by those healthcare providers who have already completed this process show that a phased approach works best. Various types of phasing are listed in this context:

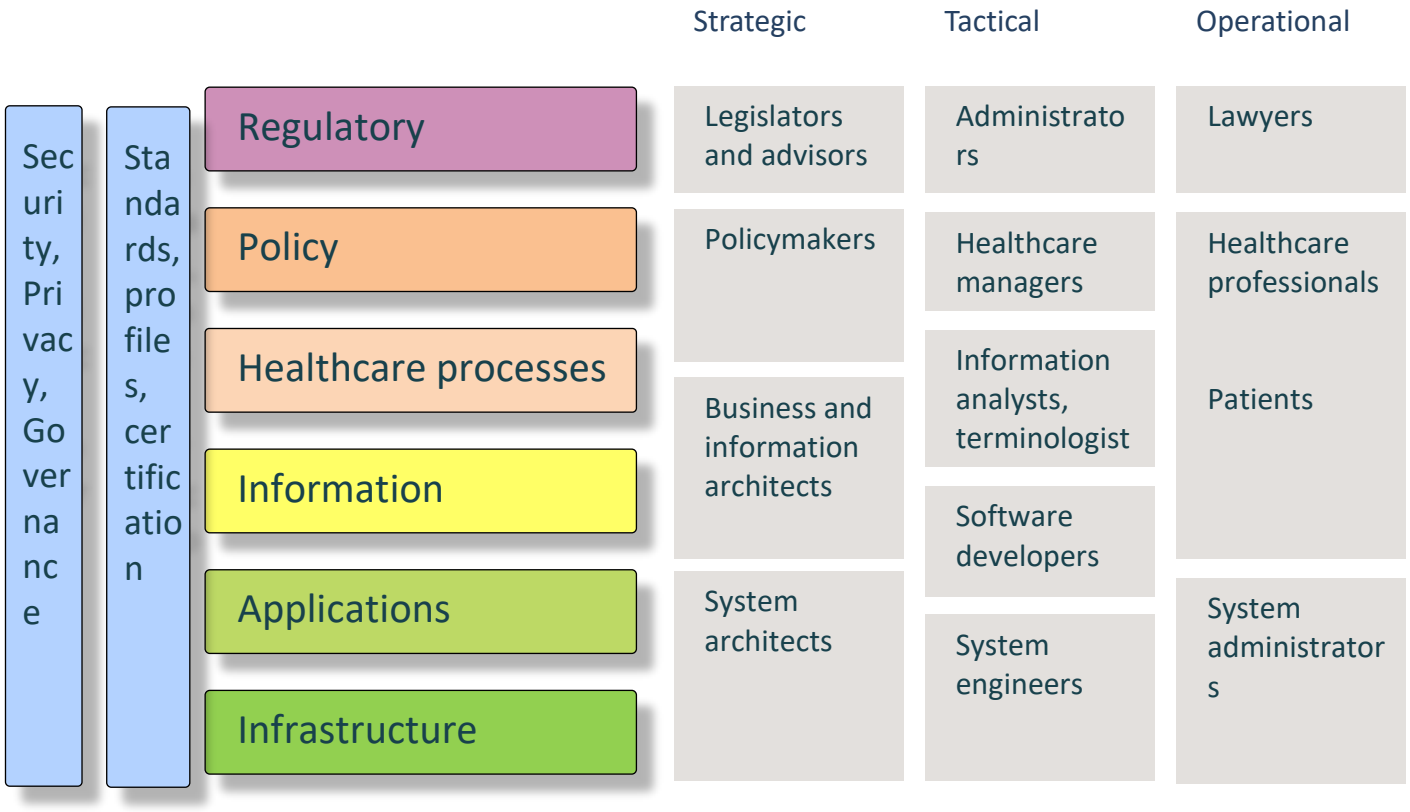
    - ✓ Start the process at the patient, registering any devices used by scanning the codes in the electronic patient record (EPR) or in a specific subsystem that is integrated with the EPR.
    - ✓ Start with a given product category, such as orthopaedic implants at the surgical department;
    - ✓ Start with all the medical devices used in a Cardiac Catheterization Laboratory (CCL) or other treatment room, e.g. those used for oral surgery, ophthalmology or interventional radiology;
    - ✓ Start with the patient, and include a link to inventory management and to any automatic ordering from suppliers (integrated approach).

From this point onwards, the hospitals can then expand this process to include other devices and/or departments/wards.

[13] In due course, these could be replaced by an RFID tag or an NFC tag.

5.3 Agreements on coding

If interoperability for automatic identification is to be achieved, then agreements must be reached at additional levels. The Centre of Expertise for Standardisation and eHealth's (Nictiz) interoperability model is the starting point here.



The interoperability model builds on developments and agreements within Europe, and provides clarity about what agreements have to be made with which professionals, for which aspects.

Source: Nictiz

The hospital is responsible for the following agreements:

1. (Governance) The Board of Directors is responsible for organising and implementing the agreements contained in this document.
2. (Policy) The hospital has a procedure in which the responsibilities and arrangements associated with unique coding are embedded in the institution's safety management system.
3. (Regulatory framework) The hospital has a procedure that uses the unique code the supplier imprinted on its own packaging.
4. (Policy) The hospital has a procedure by which, for each procurement, an assessment is made about whether the software package to be purchased should meet internationally accepted standards for unique coding: GS1, HIBC and ICCBBA. If this is the case, then the hospital incorporates the relevant compliance requirements for unique coding into the schedule of requirements.
5. (Policy) The hospital has a procedure in which responsibility for unique coding is clearly allocated.
6. (Policy) The hospital has a procedure that can be used to register and track medical devices throughout the entire institution. This means that:
    a. Relevant departments/wards will be involved in the introduction of the coding;
    b. Members of staff will be trained to recognise the correct code.

7. (Policy) The hospital has a procedure that leads to users being trained to register the medical devices being used. Correct registration is a vital part of the healthcare process, so it is necessary to specifically address this issue in training courses. These courses include the training given to surgical assistants and logistics personnel.
8. (Healthcare processes) The impact on healthcare processes as a result of the introduction of coding is heavily dependent on the current situation in the hospital. Accordingly, the hospital must carry out an internal impact analysis to determine the magnitude of the impact on the healthcare process and to identify the level of implementation effort required.
9. (Information) The healthcare institution has a procedure for registering relevant data by means of automatic identification (scanning the bar-code) in the data processing system, such as ERP, HIS or EPR.
10. (Applications) If we assume that the existing HIS/EPR applications need to be modified, then there is a dependency on the software suppliers' release calendars. The hospital must then agree a schedule with the software supplier (possibly in conjunction with other healthcare providers) that will make it possible to meet the two-year deadline.
11. (Infrastructure) The hospital has a procedure for retrieving master article data from the central article database and processing this in an internal data processing system, such as enterprise software (ERP), a Hospital Information System (HIS) or an Electronic Patient Record (EPR).
12. (Infrastructure) The hospital has a process for supplying/linking the relevant information recorded to the quality registers for orthopaedic and cardiac implants, for example, as well as to the national implant registry.

5.4 Consequences for IT systems

The introduction of internationally accepted standards for coding and the associated data from the UDI database will require modifications to be made to various IT systems. At the very least, this will involve the hospital information system (HIS), the electronic patient record (EPR) and the enterprise software (ERP), which will need to capture data on which medical device is being held at what location and which medical device was ultimately used in the patient. It should be possible for information to be exchanged between the enterprise software and the EPR/HIS, to establish traceability.

Only a limited number of integrated HIS/EPR systems are available on the Dutch market. The level of functionality and integration vary from one system to another, and from one system version to another. The hospital must take this into account and ensure that the above-mentioned systems meet the requirements for unique coding.

The hospital's HIS/EPR systems should be designed to handle at the very least the following medical device data:

- ✓ Unique product number
- ✓ Lot number
- ✓ Expiry date
- ✓ Serial number

The hospital's ERP system must be able to process the following data from the bar-code and the central Data Source article database. This involves the following fields:

- ✓ Unique supplier number
- ✓ Supplier's name
- ✓ Unique product number
- ✓ Lot number
- ✓ Serial number
- ✓ Product name
- ✓ Packaging type (pallet, outer box, items etc.)

- ✓ Number in packaging
- ✓ Indicator Lot No. Y/N

For technical specifications, please refer to the relevant standardisation organisation.

5.5 Timeline

Included in the schedule of requirements submitted to software suppliers	
Code scanning of the list	1 July 2018
Code scanning extension of the list	To be determined after 1 July 2018

5.6 Transitional period

The implementation plan contains additional guidance.

Appendix 1

Terms and definitions

EPR	Electronic Patient Record
ERP	Enterprise Resource Planning
HIBCC	HIBCC®, the Health Industry Business Communications Council. An internationally accredited, not-for-profit standards development organisation that is driven by the sector and that has a global reach. http://www.hibcc.org/
ICCBBA	International Council for Commonality in Blood Banking Automation. The international language for the terminology, identification, coding and labelling used for medical products of human origin, such as blood, tissue, cell therapy, breast milk, and organs. https://www.iccbba.org/home
Supplier	Party that supplies products.
Lot number	Alphanumeric number that identifies a production batch. Also referred to as a 'batch number'.
Medical device	Any instrument, device, piece of equipment, substance or any other article, whether used alone or in combination, including any accessories and the software necessary for their proper functioning, that is specially intended by its manufacturer to be used for diagnostic or therapeutic purposes, and is intended to be used in human patients for the purpose of: • The diagnosis, prevention, monitoring, treatment or alleviation of disease; • The diagnosis, monitoring, treatment, alleviation of – or compensation for – injuries or handicaps; • Examining, replacing, or modifying anatomy or a physiological process; • Control of conception, in which the principal intended mechanism of action in or on the human body is not achieved by pharmacological, immunological or metabolic means, although means of this kind may be used in a support role. Source: Directive 93/42/EEC of 14 June 1993, concerning medical devices EU legislation EUR-Lex
GS1	GS1 Netherlands is a not-for-profit organisation. It is part of the international GS1 organisation, which is represented in more than 110 countries. There are more than two million affiliated companies, in 30 different sectors, throughout the world. GS1 provides international standards for unique identification and capturing and sharing data by means of bar-codes, central article databases, and electronic messages. http://www.gs1.org/healthcare https://www.gs1.nl/
Primary packaging	The packaging that is in direct contact with the product. This is the product's internal shielding. For example, the plastic bag in which an implant is wrapped.
Secondary packaging	The packaging that encloses a group of sales units or primary packaging. Secondary packaging may also contain just a single product. For example, a small box containing an implant.

Tertiary packaging	The packaging that contains one or more items of secondary packaging. Usually involving the same product. One of the formats involved, for example, is an outer box or crate.
UDI	Unique Device Identifier
Unique product number	Number used to identify a type of product. Such as a specific artificial hip model.
Serial number	Alphanumeric number that identifies a single item of a given product type.
HIS	Hospital Information System
Hospital	Party that provides healthcare. The hospital receives products.

Appendix 2

Implementation plan

NFU, NVZ, ZKN, FHI, FME and Nefemed provide a implementation plan for their members. On the sites of GS1 Nederland and HIBC a roadmap and tools are available for hospitals and suppliers.

Appendix 3

VIPP-programme

Acceleration Programme for Information Exchange between Patients & Professionals

The role of patients in their own healthcare process is changing. Patients will increasingly become partners for care professionals and hospitals, with IT as the driving force behind this process. Hospitals and institutions for specialist medical care will put this into effect by means of the Acceleration Programme for Information Exchange between Patients & Professionals (VIPP). The basic principle is that Dutch citizens will all have digital access to their own medical data by 2020.

The VIPP programme was developed by the Dutch Hospital Association (NVZ), in cooperation with the Ministry of Health, Welfare and Sport (VWS). The programme will run until the end of 2019.

Objectives of the VIPP

The programme consists of two streams: data exchange with the patient and data exchange between professionals – and with the patient – concerning medication-related issues. The following objectives have been formulated:

Patient & Information

1. At the very least, healthcare institutions must be able to provide patients with a download of medical data by 1 July 2018;
2. By 31 December 2019, every healthcare institution must have a secure patient portal and/or a link to a Personal Health Environment to which the healthcare institution can upload standardised medical data for the patient;

Patient & Medication

1. By 1 July 2018, all healthcare institutions must be able to consult an up-to-date digital medication summary (information provision) as part of the medication process in clinical and outpatient settings;
2. By 31 December 2019, all healthcare institutions must be able to supply digital medication prescriptions as a prior notice and/or as a prescription;
3. By 31 December 2019, all healthcare institutions must be able to supply patients with a standardised current medication summary (including medication agreements) on discharge, in accordance with the current medication directive.

Appendix 4

Inclusion List 2018

Implant Group	Group		Implant	Parts
Joint implants	1	1	Total hip	Acetabulum
				Femoral stem
				Inlay
				Femoral head
		2	Total knee	Femur
				Tibia
				Insert
				Patella
		3	Total ankle	Tibia
				Inlay
				Talus
		4	Total shoulder	Humeral stem
				Humeral head
				Humeral liner
				Glenoid base plate
				Glenosphere
				Glenoid component
				Metaphysis
		5	Total elbow	Humerus
				Ulna
				Radial head
				Radial stem
		6	Total wrist	Radial stem
				Radial head
				Ulnar stem
				Ulnar head
				Inlay
				Carpal plate
				Carpal stem
				Carpal head
		7	Total finger	Proximal stem
				Proximal head
				Distal stem
				Distal head

Implant Group	Group		Implant	Parts
Incontinence implants	2	1	Female sling procedure	
		2	Male sling procedure	
		3	ProAct	Left balloon
				Right balloon
		4	Sphincter implant	Cuff
				Balloon reservoir
				Pump
				Connectors
Gynecological implants	3	1	Essure	
		2	Vaginal pelvic mesh	
Heart implants	4	1	Pacemakers and leads	Pacemakers
				Leads
		2	Implantable Cardioverter Defibrillator	ICD
				Leads
		3	Ventricular assist devices (RVAD-LVAD)	
		4	Baroreceptor stimulation device	
		5	Heart valves	
		6	Intracardiac devices:	
			a. ASD closure devices	
			b. VSD closure devices	
			c. PDA closure devices	
			d. Left atrial appendage	
			e. Coronary vascular plugs	
			f. MitraClip	
		7	Loop recorder	
Brain stimulators	5	1	Deep brain stimulator	Intracranial electrode
				Subcutaneous pulse generator
				Subcutaneous extensions

Implant Group	Group		Implant	Parts
Neurostimulators	6	1	Neurostimulator for fecal incontinence	
		2	Neurostimulator for constipation	
		3	Neurostimulators for pain	Epidural lead
				Subcutaneous extensions
				Subcutaneous IPG
		4	Neurostimulators for bladder control	Neurostimulator
				Leads
		5	Neurostimulators for foot	
		6	Vagus nerve stimulator	Pulse generator
				Electrode
Medication pumps	7	1	Implantable insulin pump	
		2	Intrathecal drug delivery system (IDDS)	Intrathecal catheter
				Subcutaneous port
				Subcutaneous pump
		3	Baclofen pump for ITB	
Hearing implants	8	1	Cochlear implant (CI)	
		2	Active middle ear implant	
		3	Active Transcutaneous Bone Conduction Implant	
Vascular implants	9	1	Vascular stents (noncoronary):	
			a. Drug eluting stents (noncoronary)	
			b. Bioresorbable stents (noncoronary)	
			c. Vascular stents (intracranial): Flow diverters	
			d. Coronary stents: all coronary stents, including drug eluting, and bioresorbable stents	
		2	Intrathoracic vascular implants including thoracic aortic grafts, open stent grafts, thoracic stent grafts	
		3	Abdominal aortic grafts	
Lung implants	13	1	Pulmonary valve	
		2	Lung volume reduction coil	
		3	Airway stent	

Implant Group	Group		Implant	Parts
Plastic surgery implants	14	1	Breast implant	
		2	Buttock implant	
		3	Testicular implant	
		4	Penile implant (semi-rigid)	
		5	Penile implant (inflatable)	Cuff
				Balloon reservoir
				Pump
				Connectors

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EHIBCC
The European Health Industry Business Communications Council. The EHIBCC is an ISO-accredited organisation for bar-coding. The bar-code was specially developed, in 1983, (from within GS1) for the medical sector within the healthcare industry. Its application provides support for hospitals, pharmacies, dentists, the pharmaceutical industry and individual health workers. This primarily involves 'tracking and tracing', patient safety, and applications within the healthcare industry. The bar-code system, which is ISO certified, has been included in the current US Food and Drug Administration (FDA) directive.
http://www.hibcc.org/
www.ehibcc.com

GS1
GS1 Netherlands is a not-for-profit organisation. It is part of the international GS1 organisation, which is represented in more than 110 countries. There are more than two million affiliated companies, in 30 different sectors, throughout the world. GS1 provides international standards for unique identification and capturing and sharing data by means of bar-codes, central article databases, and electronic messages.
http://www.gs1.org/healthcare
https://www.gs1.nl/

ICCBBA
The international language for the terminology, identification, coding and labelling used for medical products of human origin, such as blood, tissue, cell therapy, breast milk, and organs.
https://www.iccbba.org/home