ANNEX VI

INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF DEVICES AND ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLES 26(3) AND 28, CORE DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE TOGETHER WITH THE UDI-DI IN ACCORDANCE WITH ARTICLES 25 AND 26 AND THE UDI SYSTEM

PART A

INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF DEVICES AND ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLES 26(3) AND 28

Manufacturers or, when applicable, authorised representatives, and, when applicable, importers shall submit the information referred to in Section 1 and shall ensure that the information on their devices referred to in Section 2 is complete, correct and updated by the relevant party.

1. Information relating to the economic operator

1.1. type of economic operator (manufacturer, authorised representative, or importer),

1.2. name, address and contact details of the economic operator,

1.3. where submission of information is carried out by another person on behalf of any of the economic operators mentioned under Section 1.1, the name, address and contact details of that person,

1.4. name address and contact details of the person or persons responsible for regulatory compliance referred to in Article 15,

2. Information relating to the device

2.1. Basic UDI-DI,

2.2. type, number and expiry date of the certificate issued by the notified body and the name or identification number of that notified body and the link to the information that appears on the certificate and was entered by the notified body in the electronic system on notified bodies and certificates,

2.3. Member State in which the device shall or has been placed on the market in the Union,

2.4. in the case of class B, class C or class D devices: Member States where the device is or is to be made available,

2.5. presence of tissues, cells, or, their derivatives, of human origin (y/n),

2.6. presence of tissues, cells or their derivatives of animal origin as referred to in Regulation (EU) No 722/2012(y/n),

2.7. presence of cells or substances of microbial origin (y/n),

2.8. risk class of the device,

2.9. where applicable, the single identification number of the performance study,

2.10. in the case of devices designed and manufactured by another legal or natural person as referred in Article 10(14), the name, address and contact details of that legal or natural person,

2.11. in the case of class C or D devices, the summary of safety and performance,

2.12. status of the device (on the market, no longer placed on the market, recalled, field safety corrective Action initiated),

2.13. indication as to whether the device is a 'new' device.

A device shall be considered to be 'new' if:

(a) there has been no such device continuously available on the Union market during the previous three years for the relevant analyte or other parameter;

(b) the procedure involves analytical technology not continuously used in connection with a given analyte or other parameter on the Union market during the previous three years.

2.14. indication as to whether the device is intended for self-testing or near-patient testing.

PART B

CORE DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE TOGETHER WITH THE UDI-DI IN ACCORDANCE WITH ARTICLES 25 AND 26

The manufacturer shall provide to the UDI database the UDI-DI and the following information relating to the manufacturer and the device:

1. quantity per package configuration,

2. the Basic UDI-DI as referred to in Article 24(6) and any additional UDI-DIs,

3. the manner in which production of the device is controlled (expiry date or manufacturing date, lot number, serial number),

4. if applicable, the 'unit of use' UDI-DI (where a UDI is not labelled on the device at the level of its 'unit of use', a 'unit of use' UDI-DI shall be assigned so as to associate the use of a device with a patient),

5. name and address of the manufacturer, as indicated on the label,

6. the SRN issued in accordance with Article 28(2),

7. if applicable, name and address of the authorised representative (as indicated on the label),

8. the medical device nomenclature code as provided for in Article 23,

9. risk class of the device,

10. if applicable, name or trade name,

11. if applicable, device model, reference, or catalogue number,

12. additional product description (optional),

13. if applicable, storage and/or handling conditions (as indicated on the label or in the instructions for use),

14. if applicable, additional trade names of the device,

15. labelled as a single use device (y/n),

16. if applicable, the maximum number of reuses,

17. device labelled sterile (y/n),

18. need for sterilisation before use (y/n),

19. URL for additional information, such as electronic instructions for use (optional),

20. if applicable, critical warnings or contra-indications,

21. status of the device (on the market, no longer placed on the market, recalled, field safety action initiated).

PART C

THE UDI SYSTEM

1. Definitions

Automatic identification and data capture (‘AIDC’)

AIDC is a technology used to automatically capture data. AIDC technologies include bar codes, smart cards, biometrics and RFID.

Basic UDI-DI

The Basic UDI-DI is the primary identifier of a device model. It is the DI assigned at the level of the device unit of use. It is the main key for records in the UDI database and is referenced in relevant certificates and EU declarations of conformity.

Unit of Use DI

The Unit of Use DI serves to associate the use of a device with a patient in instances in which a UDI is not labelled on the individual device at the level of its unit of use, for example in the event of several units of the same device being packaged together.

Configurable device

A configurable device is a device that consists of several components which can be assembled by the manufacturer in multiple configurations. Those individual components may be devices in themselves.

Configuration

Configuration is a combination of items of equipment, as specified by the manufacturer, that operate together as a device to achieve an intended purpose. The combination of items may be modified, adjusted or customised to meet specific needs.

UDI-DI

The UDI-DI is a unique numeric or alphanumeric code specific to a model of device and that is also used as the ‘access key’ to information stored in a UDI database.

Human Readable Interpretation (HRI)

HRI is a legible interpretation of the data characters encoded in the UDI carrier.

Packaging levels

Packaging levels means the various levels of device packaging that contain a fixed quantity of devices, such as a carton or case.
Production Identifier (UDI-PI)

The UDI-PI is a numeric or alphanumeric code that identifies the unit of device production.

The different types of UDI-PI(s) include serial number, lot number, software identification and manufacturing or expiry date or both types of date.
Radio Frequency Identification ('RFID')

RFID is a technology that uses communication through the use of radio waves to exchange data between a reader and an electronic tag attached to an object, for the purpose of identification.
Shipping containers

A shipping container is a container in relation to which traceability is controlled by a process specific to logistics systems.
Unique Device Identifier ('UDI')

The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific device on the market. The UDI is comprised of the UDI-DI and the UDI-PI.

The word 'Unique' does not imply serialisation of individual production units.
UDI carrier

The UDI carrier is the means of conveying the UDI by using AIDC and, if applicable, its HRI.

UDI carriers include, *inter alia*, ID/linear bar code, 2D/Matrix bar code, RFID.

2. General requirements

2.1. The affixing of the UDI is an additional requirement — it does not replace any other marking or labelling requirements laid down in Annex I to this Regulation.

2.2. The manufacturer shall assign and maintain unique UDIs for its devices.

2.3. Only the manufacturer may place the UDI on the device or its packaging.

2.4. Only coding standards provided by issuing entities designated by the Commission pursuant to Article 24(2) may be used.

3. The UDI

3.1. A UDI shall be assigned to the device itself or its packaging. Higher levels of packaging shall have their own UDI.

3.2. Shipping containers shall be exempted from the requirement in Section 3.1. By way of example, a UDI shall not be required on a logistics unit; where a healthcare provider orders multiple devices using the UDI or model number of individual devices and the manufacturer places those devices in a container for shipping or to protect the individually packaged devices, the container (logistics unit) shall not be subject to UDI requirements.

3.3. The UDI shall contain two parts: a UDI-DI and a UDI-PI.

3.4. The UDI-DI shall be unique at each level of device packaging.

3.5. If a lot number, serial number, software identification or expiry date appears on the label, it shall be part of the UDI-PI. If there is also a manufacturing date on the label,

it does not need to be included in the UDI-PI. If there is only a manufacturing date on the label, this shall be used as the UDI-PI.

3.6. Each component that is considered to be a device and is commercially available on its own shall be assigned a separate UDI unless the components are part of a configurable device that is marked with its own UDI.

3.7. Kits shall be assigned and bear their own UDI.

3.8. The manufacturer shall assign the UDI to a device following the relevant coding standard.

3.9. A new UDI-DI shall be required whenever there is a change that could lead to misidentification of the device and/or ambiguity in its traceability. In particular, any change of one of the following UDI database data elements shall require a new UDI-DI:

(a) Name or trade name,

(b) device version or model,

(c) labelled as single use,

(d) packaged sterile,

(e) need for sterilization before use,

(f) quantity of devices provided in a package,

(g) critical warnings or contra-indications.

3.10. Manufacturers that repackage or relabel devices with their own label shall retain a record of the original device manufacturer's UDI.

4. UDI carrier

4.1. The UDI carrier (AIDC and HRI representation of the UDI) shall be placed on the label and on all higher levels of device packaging. Higher levels do not include shipping containers.

4.2. In the event of there being significant space constraints on the unit of use packaging the UDI carrier may be placed on the next higher packaging level.

4.3. For single use class A and class B devices packaged and labelled individually, the UDI carrier shall not be required to appear on the packaging but it shall appear on a higher level of packaging e.g. a carton containing several packages. However, when the healthcare provider is not expected to have access, in cases such as in home healthcare settings, to the higher level of device packaging, the UDI shall be placed on the packaging.

4.4. For devices exclusively intended for retail point of sale, the UDI-PIs in AIDC shall not be required to appear on the point of sale packaging.

4.5. When AIDC carriers other than the UDI carrier are part of the product labelling, the UDI carrier shall be readily identifiable.

4.6. If linear bar codes are used, the UDI-DI and UDI-PI may be concatenated or non-concatenated in two or more bar codes. All parts and elements of the linear bar code shall be distinguishable and identifiable.

4.7. If there are significant constraints limiting the use of both AIDC and HRI on the label, only the AIDC format shall be required to appear on the label. For devices intended to be used outside healthcare facilities, such as devices for home care, the HRI shall however appear on the label even if this results in there being no space for the AIDC.

4.8. The HRI format shall follow the rules of the UDI code-issuing entity.

4.9. If the manufacturer is using RFID technology, a linear or 2D bar code in line with the standard provided by the issuing entities shall also be provided on the label.

4.10. Devices that are reusable shall bear a UDI carrier on the device itself. The UDI carrier for reusable devices that require disinfection, sterilisation or refurbishing between patient uses shall be permanent and readable after each process performed to make the device ready for the subsequent use throughout the intended lifetime of the device.

4.11. The UDI carrier shall be readable during normal use and throughout the intended lifetime of the device.

4.12. If the UDI carrier is readily readable or scannable through the device's packaging, the placing of the UDI carrier on the packaging shall not be required.

4.13. In the case of single finished devices made up of multiple parts that must be assembled before first use, it shall be sufficient to place the UDI carrier on only one part of each device.

4.14. The UDI carrier shall be placed in a manner such that the AIDC can be accessed during normal operation or storage.

4.15. Bar code carriers that include both a UDI-DI and a UDI-PI may also include essential data for the device to operate or other data.

5. General principles of the UDI database

5.1. The UDI database shall support the use of all core UDI database data elements referred to in Part B of this Annex.

5.2. Manufacturers shall be responsible for the initial submission and updates of the identifying information and other device data elements in the UDI database.

5.3. Appropriate methods/procedures for validation of the data provided shall be implemented.

5.4. Manufacturers shall periodically verify the correctness of all of the data relevant to devices they have placed on the market, except for devices that are no longer available on the market.

5.5. The presence of the device UDI-DI in the UDI database shall not be assumed to mean that the device is in conformity with this Regulation.

5.6. The database shall allow for the linking of all the packaging levels of the device.

5.7. The data for new UDI-DIs shall be available at the time the device is placed on the market.

5.8. Manufacturers shall update the relevant UDI database record within 30 days of a change being made to an element, which does not require a new UDI-DI.

5.9. Internationally accepted standards for data submission and updates shall, wherever possible, be used by the UDI database.

5.10. The user interface of the UDI database shall be available in all official languages of the Union. The use of free-text fields shall, however, be minimised in order to reduce translations.

5.11. Data relating to devices that are no longer available on the market shall be retained in the UDI database.

6. Rules for specific device types

6.1. Reusable devices that are part of kits and that require cleaning, disinfection, sterilisation or refurbishing between uses

6.1.1. The UDI of such devices shall be placed on the device and shall be readable after each procedure to make the device ready for the next use;

6.1.2. The UDI-PI characteristics such as the lot or serial number shall be defined by the manufacturer.

6.2. Device software

6.2.1. UDI assignment Criteria

The UDI shall be assigned at the system level of the software. Only software which is commercially available on its own and software which constitutes a device in itself shall be subject to that requirement.

The software identification shall be considered to be the manufacturing control mechanism and shall be displayed in the UDI-PI.

6.2.2. A new UDI-DI shall be required whenever there is a modification that changes:

(a) the original performance,

(b) the safety or the intended use of the software.

(c) interpretation of data.

Such modifications include new or modified algorithms, database structures, operating platform, architecture or new user interfaces or new channels for interoperability.

6.2.3. Minor software revisions shall require a new UDI-PI and not a new UDI-DI:

Minor software revisions are generally associated with bug fixes, usability enhancements that are not for safety purposes, security patches or operating efficiency.

Minor software revisions shall be identified by a manufacturer-specific form of identification.

6.2.4. UDI placement criteria for software

(a) where the software is delivered on a physical medium, for example via *a* CD or DVD, each packaging level shall bear the human readable and AIDC representation of the complete UDI. The UDI that is applied to the physical medium containing the software and its packaging shall be identical to the UDI assigned to the system level software;

(b) the UDI shall be provided on a readily accessible screen for the user in an easily-readable plain-text format such as an ‘about’ file, or included on the start-up screen;

(c) software lacking a user interface such as middleware for image conversion, shall be capable of transmitting the UDI through an application programming interface (API);

(d) only the human readable portion of the UDI shall be required in electronic displays of the software. The marking of UDI using AIDC shall not be required in the electronic displays such as ‘about’ menu, splash screen, etc.;

(e) the human readable format of the UDI for the software shall include the application identifiers (AI) for the standard used by the issuing entities, so as to assist the user in identifying the UDI and determining which standard is being used to create the UDI.