MEDICAL GASES

UNIQUE DEVICE IDENTIFIER (UDI) FOR MEDICAL DEVICES USED IN THE GAS INDUSTRY

Doc 227/20

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Prepared by WG-15 Medical Equipment

Disclaimer

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1 Introduction

On the 25th May 2017, the new European regulation EU 2017/745 on Medical Devices, (MDR) came into force. It will come into full application on the 26th May 2020 and replaces the current Directive 93/42/EEC and its national transpositions [1][1,2].

It introduces, among others, totally new requirements concerning the registration and traceability of medical devices put on the market via an identification system based on a Unique Device Identifier (UDI).

This UDI system is expected by the European Commission to facilitate easier traceability of medical devices, significantly enhance the effectiveness of the post-market safety-related activities for devices, allow for better monitoring by competent authorities, help to reduce medical errors, fight against falsified devices, improve purchasing and waste disposal policies and stock-management by health institutions and other economic operators.

Article 27 of the MDR lays down that the UDI system shall consist of:

- production of a UDI by the manufacturer of the device;
- placing of the UDI carrier on the label of the device or on its packaging;
- storage of the UDI by economic operators; and
- establishment of an electronic database for UDIs part of the EUDAMED database.

2 Scope and purpose

2.1 Scope

This publication applies to the medical devices put on the market by the gas manufacturers according to the new medical device regulation EU 2017/745 [1] and concerns the implementation of the requirements related to the UDI system.

2.2 Purpose

This publication has been prepared to enable EIGA members to understand the overall UDI system and to efficiently implement these new requirements for the medical devices they are putting on the market as the legal manufacturer in compliance with the regulatory timeframe.

It addresses the production of the UDI, the associated labelling and the registration of the medical devices in the UDI - EUDAMED database with a focus on the specificities of medical device gases and medical pipeline systems.

This publication has been prepared in September 2019 with the information available at that time. It will be updated as significant new European guidelines are published.

[1] References are shown by bracketed numbers and are listed in order of appearance in the reference section.

3 Definitions

For the purposes of this publication, the following definitions apply.

3.1 Publication terminology

3.1.1 Shall

Indicates that the procedure is mandatory. It is used wherever the criterion for conformance to specific recommendations allows no deviation.

3.1.2 Should

Indicates that the procedure is recommended.

3.1.3 May

Indicates that the procedure is optional.

3.1.4 Will

Is used only to indicate the future, not a degree of requirement.

3.1.5 Can

Indicates a possibility or ability.

3.2 Technical definitions

3.2.1 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.

3.2.2 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.

Example: Medical Gas Pipelines Systems.

3.2.3 Human Readable Interpretation (‘HRI’)

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

3.2.4 Issuing entity

Legal entity enabled by means of implementing acts of The European Commission to operate a system for assignment of UDIs.

3.2.5 Legacy device

Devices, which can continue to be placed on the market under Directive certificates by virtue of Article 120(3) of MDR after the MDR application dates.

3.2.6 Model

One medical device or a family of medical devices with variations that have shared characteristics (variants) and have a common CE technical documentation.

3.2.7 Unit of use (UoU)

The UoU refers to an individual medical device in instances when a UDI is not labelled at the level of the device, for example in the event of several units of the same device being packaged together (e.g. several units contained in a plastic bag) or when the device dimension, shape or material make it impossible to be labelled. Its purpose is to associate the use of a device to/on a patient.

3.2.8 Unique Device Identifier (UDI)

A series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market.
NOTE: UDI-DI: DI stands for Device Identifier
UDI-PI: PI stands for Production Identifier

3.2.9 UDI Carrier

The UDI Carrier is the means to convey the UDI by using AIDC and, if applicable, its HRI.
Note: Carriers can include 1D-linear bar code, 2D-matrix bar code, RFID, etc…

4 EUDAMED database: registration of the operator and devices

EUDAMED is a medical device database, managed by the European commission, which will gather all the regulatory information concerning the medical devices put on the market.

EUDAMED is designed, as defined in Article 33 of the MDR, for the following purposes:

- enable the public to be adequately informed about devices placed on the market, the corresponding certificates issued by notified bodies and about the relevant economic operators;
- enable unique identification of devices within the internal market and to facilitate their traceability;
- enable the public to be adequately informed about clinical investigations and to enable sponsors of clinical investigations to comply with the obligations of this regulation;
- enable manufacturers to comply with the information obligations laid down in this regulation; and
- enable the Competent Authorities (CAs) of the Member-States and the Commission to carry out their tasks relating to this regulation on a well-informed basis and to enhance the cooperation between them.

The structure of EUDAMDED and interaction with stakeholders can be represented in Figure 1:

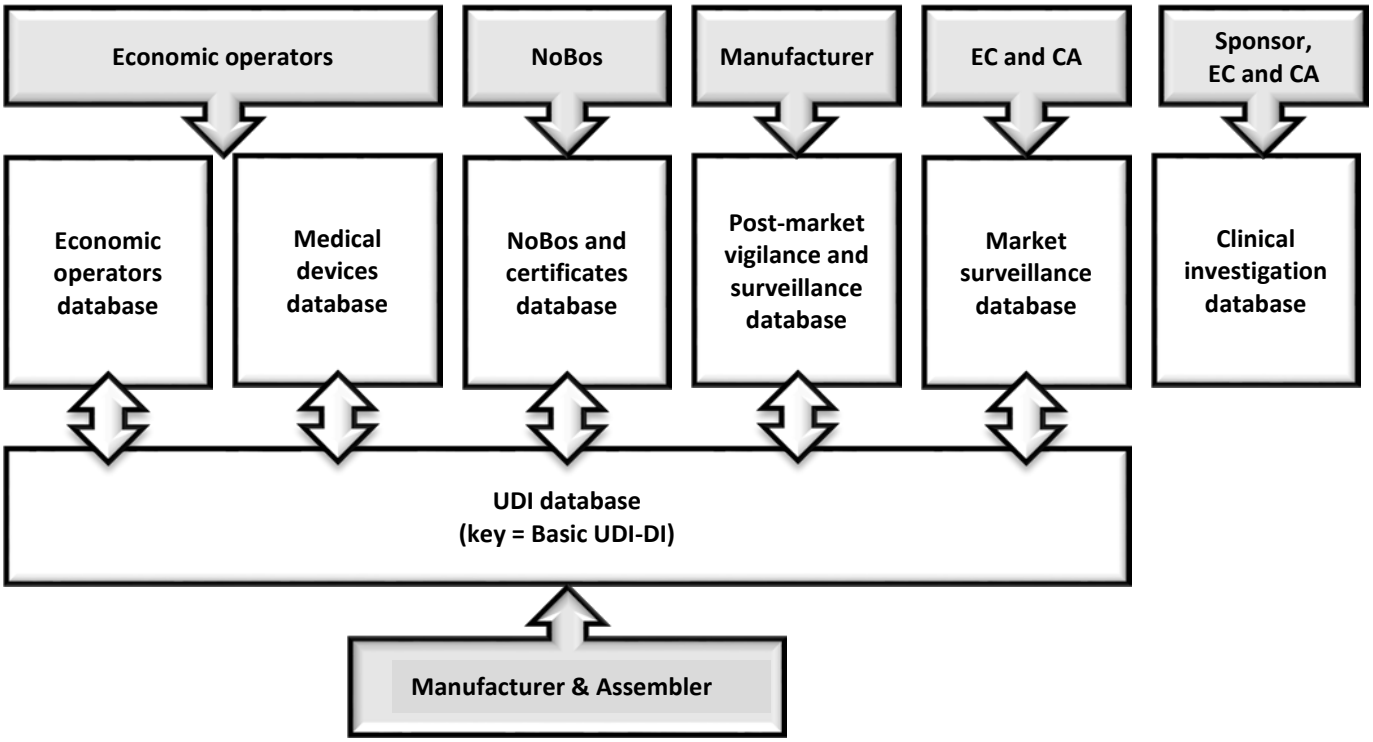

Figure 1 – EUDAMED structure

5 Understanding UDI

5.1 General overview

The UDI for a medical device is made up of three parts:

- Basic-UDI-DI;
- UDI-DI; and
- UDI-PI.

5.1.1 Basic UDI-DI

The Basic UDI-DI is the main access key for device-related information in the EUDAMED database and it is referenced in relevant documentation, for example, certificates, EU declaration of conformity, technical documentation and summary of safety and clinical performance. It is intended to identify and connect devices with the same intended purpose, risk class, essential design and manufacturing characteristics.

It is independent/separate from the packaging/labelling of the devices and it does not appear on any trade item (packaging or labelling). Any Basic UDI-DI shall identify the devices (model and variants) covered by that Basic UDI-DI in a unique manner.

One Basic UDI-DI can have several associated UDI-DIs (see below).

NOTE The length of the Basic UDI-DI is limited to 25 characters.

5.1.2 UDI-DI

The UDI-DI is a unique numeric or alphanumeric code specific to a medical device (or a variant of medical device in a family) and is used as the access key to information stored in an UDI database.

The UDI-DIs are the static information that will appear on the packaging/labelling of each device.

One UDI-DI is associated to only one Basic UDI-DI.

5.1.3 UDI-PI

The UDI-PI is a numeric or alphanumeric code that identifies the unit of device production. Information contained in the UDI-PI can include a serial number, a lot number, a software identification and the manufacturing and/or expiry date, etc.

The UDI-PIs will appear on the packaging/labelling of each device, together with the UDI-DI.

The summary is shown in Figure 2.

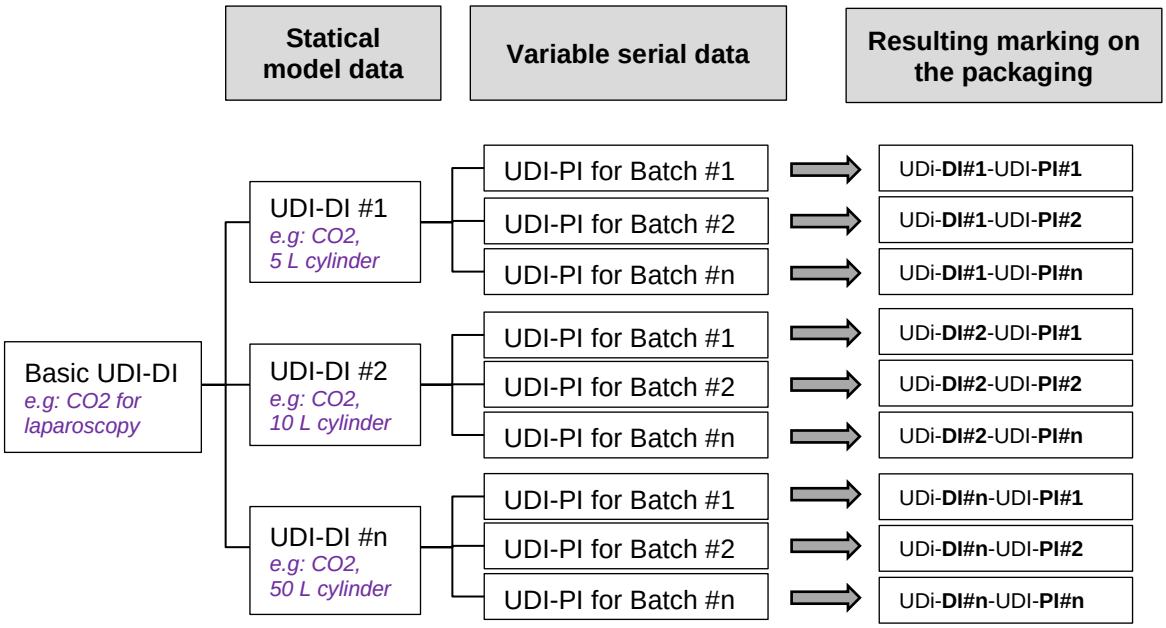

Figure 2 – UDI summary

5.2 Content of the Basic-UDI-DI

Any Basic UDI-DI shall identify the devices (group) covered by that Basic UDI-DI in a unique manner. It shall be reported on:

- certificates (notified bodies);
- declaration of conformity;
- technical documentation;
- summary of safety and clinical performance; and
- certificates of free sale.

For example, carbon dioxide for laparoscopy includes all cylinder sizes and all label languages.

5.3 Content of the UDI-DI

The UDI-DI is specifically linked to the device model or specific variant in the case of a family of devices. It shall be included on the device label and on the external packaging, together with the UDI-PI.

If there are several levels of packaging, each level has its own UDI-DI.

An example is a box of ten valves with integrated pressure regulator (VIPR). All VIPRs are marked with the same UDI-DI and the box of 10 is labelled with a different UDI-DI.

The UDI-DI should include among other information (the exhaustive list is shown in Annex VI.B of the MDR):

- quantity per package configuration;
- clinical size (including volume, length, thickness, diameter), if appropriate,
- risk class of the device;
- storage and / or handling conditions, where appropriate; and
- critical warnings or contraindications, if applicable.

Additional information can be added by the manufacturer.

If the device contains carcinogenic, mutagenic or reprotoxic substances or substances with endocrine disrupting properties in a concentration above 0.1% weight by weight (w/w), the additional information required for labelling from Annex I (point 10.4.5) shall be added.

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. Such as in the case of any change of the following elements:

- name or trade name;
- device version or model;
- single/multiple use changes;
- packaging sterility changes for example, sterile/to be sterilized;
- quantity of devices provided in a package; and
- critical warnings or contraindications.

5.4 Content of the UDI-PI

The UDI-PI should include, where applicable:

- Batch/Lot number
  Format as defined by the manufacturer

- Expiry and/or Manufacturing date
  Format of the date: YYYY-MM

- Serial number
  Format as defined by the manufacturer

- Software version
  Format as defined by the manufacturer

The UDI-PI is not part of the information to be uploaded on EUDAMED.

5.5 Legacy devices

The UDI shall only be used for those devices CE-marked according to the requirements of the MDR.

For legacy devices with a valid certificate according to MDD during the transition period, the DI will be assigned automatically by the EUDAMED system and not by the manufacturer, as for medical devices complying with MDR. The DI will be unique for a given legacy device.

The manufacturer of the legacy device will be also responsible for entering the directive certificate details (NoBo number, certificate number, revision number and expiry date) in EUDAMED since they will not be registered by the NoBos.

Once a legacy device fulfils the requirements of the MDR, it needs to be registered again in EUDAMED, as a new device.

6 Label characteristics

The UDI carrier (label) shall include both the UDI-DI and the UDI-PI.

If linear bar codes are used, the MDR mentions that the UDI-DI and UDI-PI may be concatenated or non-concatenated in two or more bar codes and that, in this case, all parts and elements of the linear bar code shall be distinguishable and identifiable.

Therefore, the current understanding of EIGA WG-15 it that is allowed to split the UDI-DI and the UDI-PI in two different carriers (e.g. in two different lines or labels).

The UDI Carrier (AIDC and HRI) shall be on the label or on the device itself and on all higher levels of device packaging.

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

Higher levels of packaging shall have their own unique UDI.

Shipping containers are exempted from the UDI requirement, for example, cylinder pallets and road tankers.

The UDI shall appear in a plain-text version/human readable information (HRI) and in a form that uses AIDC technology.

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.

For other specific requirements related to the UDI carrier, please consult Section 4 of Annex VI Part C of the MDR.

7 Issuing entities

The issuing entities designated by the Commission are the following:

Issuing entity	**Link**	**Characteristics**
GS1	http://www.gs1.org/	It uses the GTIN code which could be used for all MD (excluded those derived or containing human cells and tissues)
HIBCC	http://www.hibcc.org/	It uses the HIBC code which could be used for all MD (excluded those derived or containing human cells and tissues)
ICCBBA	https://www.iccbba.org/	It uses the ISBT 128 code and it is mainly used for products derived or containing human cells and tissues.
IFA	https://www.ifaffm.de/en/ifa-gmbh.html	It uses a Pharmacy Product Number (PPN) coded according to IFA's Coding System conforming with the MDR.

8 Implementation dates

To date, the implementation dates defined by the European Commission for the placing of UDI-carriers on the label of medical devices are the following:

- Class III: 26th May 2021
- Class IIa and IIb: 26th May 2023
- Class I: 26th May 2025

9 Application of the UDI to the gases industry

9.1 Application of the UDI to cylinders and dewars

In the case of medical device gases, since the content is intended for several patients and it is not possible to make a UDI appear on the content delivered to a single patient, the UoU UDI-DI (virtual code) should be assigned when creating the UDI-DI.

The UDI-DI is then assigned to the single capacity of the package and could therefore be displayed on the product label, while the UDI-PI could be displayed with the lot label.

9.1.1 For Medical Device gases in cylinder:

a) Basic UDI-DI

This refers to the group of devices of the same category, typically the gas in its intended use, for example carbon dioxide laparoscopy.

b) Unit of Use UoU-DI

This refers to the gas contained in the package (cylinder) as a medical device.

By convention, EIGA proposes to use 1 litre (litre of water of capacity of the cylinder) for representing the UoU because it is the usual means of differentiating the different sizes of containers.

For example, when registering in EUDAMED the 5 litres carbon dioxide cylinder, the UoU mentioned will be 5.

c) UDI-DI on base package or configurable

One UDI-DI by cylinder size / valve outlet / specific label (language).

d) UDI-PI

Production batch.

e) Shipping package

The cylinders casters shall not have an UDI because not considered as a medical package (only for logistic purpose).

9.1.2 For medical device gases in dewar (full VS empty delivery)

a) Basic UDI-DI

This refers to the group of devices of the same category, typically the gas in its intended use, for example liquid nitrogen for cryotherapy.

b) Unit of Use UoU-DI

This refers to the gas contained in the package (dewar) as a medical device.

By convention, EIGA proposes to use 1 litre (litre of water of capacity of the dewar) for representing the UoU because it is the usual means of differentiating the different sizes of containers.

For example, when registering in EUDAMED the 5 litres nitrogen dewar, the UoU mentioned will be 5.

c) UDI-DI o base package or configurable

One UDI-DI by dewar size / specific label (language).

d) UDI-PI

Production batch.

e) Shipping package

The dewars casters shall not have an UDI because not considered as a medical package (only for logistic purpose).

9.2 Applying UDI to liquid gases delivered by cryogenic tankers

This case corresponds to the delivery of a medical device without primary package. The road tanker or mobile vessel used by the gas manufacturer is just a means of delivering the liquid (shipping container). The user is providing the package to be filled with the medical device (liquid gas).

This is a very special and unusual situation in the field of medical devices. To address this very specific case, EIGA propose by convention to use one UDI-DI irrespective the mobile vessel used for the delivery.

This UDI-DI and the UDI-PI shall appear on the document provided by the gas supplier with each unique delivery (e.g. delivery note or analysis certificate).

9.3 For Medical Device gases in bulk or loose

a) Basic UDI-DI

This refers to the group of devices of the same category, typically the gas in its intended use, for example liquid nitrogen for cryotherapy.

b) Unit of Use UoU-DI

This refers to medical device gas, delivered to the user.

By convention, EIGA proposes to use 1 litre for representing the UoU when registering the device in EUDAMED.

c) UDI-DI on base package or configurable

No base package in the case of liquid gases delivered by cryogenic tankers or mobile vessel

d) UDI-PI

Production batch.

e) Shipping package

The road tank, minibulk, dewar shall not have an UDI because not considered as a medical package (only for logistic purpose).

This approach provides all the traceability information for each batch of liquid gas, allowing effective recall in the event of a non-conforming product being identified.

9.4 Applying UDI to medical gas pipeline systems and similar installations

A basic UDI-DI has to be assigned to the configurable device as a whole, having the same group of components and the same intended purpose.

Examples given in the MDR include computerized tomography (CT) systems, ultrasound systems, anaesthesia systems, physiological monitoring systems and radiological information systems (RIS), and therefore, by analogy, medicinal gas distribution systems, vacuum and anaesthetic gases scavenging systems.

Basic UDI-DI is assigned to groups of configurations and not for individual configuration within the group. By group of configurations is meant the set of possible configurations of a given device as described in the technical documentation.

Example of group of a configuration:

> Medical air distribution system made by: source(s) of supply (manifolds for the connection of cylinders, compressors, including filters and switch over system, mixers), valves, pressure regulators, reduction panels, pipes, terminal units, alarms, etc.

NOTE The complete list of components shall be specified by the manufacturer in its technical file.

Each component, sub-system or accessory that is considered a medical device on its own needs a separate UDI.

Examples of such components:

> Terminal units, manifolds, source of supply with compressors for medical air, etc.

A UDI-PI is allocated to each individual system installed, so the complete UDI can be as follows.

9.5 For medical gas pipeline systems

a) Basic UDI-DI

Pipeline systems for medical gases (all gases).

b) UDI-DI on base package or configurable

One UDI-DI for each configuration (e.g. pipeline system).

Example:

> UDI-DI for the oxygen distribution system made by: list of elements from the connection valve to the terminal units)
>
> UDI-DI for the vacuum distribution system made by: list of elements from the vacuum pump to the terminal outlets)
>
> Etc.

c) UDI-PI

Installation/realization identification (e.g. project number, executive drawing number or similar with identification of the gas lines)

Both UDI-DI and UDI-PI are affixed to the assembly that most likely does not get changed during the lifetime of the system. (Ref Annex VI.B points 1, 6.4).

Examples:

> UDI labels affixed on the reduction panel, close by the main shut off valve, etc.

NOTE The manufacturer shall identify in its technical file where to affix the UDI label.

If a later change of component results in a new model/version of the configurable device, then that would trigger a new system UDI-DI (as well as new system UDI-PI, in cases of changes to already installed systems). If that change did not result in a new version/model, there would be no change in system UDI-DI (or system UDI-PI).

Example with change only in the UDI-DI:

> The manufacturer has not foreseen in its technical file the possibility of an alternative configuration such as the use of mixer for the medical air centralized distribution pipeline distribution system, the change in the technical file will trigger a request of a new UDI-DI.

No existing installations are affected by this change therefore their UDI-DI or UDI-PI will remain unchanged.

Example with change in both UDI-DI and UDI-PI:

> A manufacturer is requested by the hospital to upgrade its installed medical air distribution system ‘Model A’ by adding the carbon dioxide sensor as requested by ISO 7396-1:2016. The manufacturer upgrades is technical file with this new configuration ‘Model B’. A new UDI-DI needs to be attributed to the Model B. When doing the upgrade in the hospital of the already existing installation with the carbon dioxide sensor, a new UDI-PI is given as well.

A new UDI-DI is not required when the activities performed do not result in a change/modification in performance, safety and/or intended use, of a previously marketed device. The activities shall be performed in accordance with the manufacturer’s instructions."

Example:

> An installed medical air distribution system has terminal units which have reached the end of their life and are replaced with a newer model by the original manufacturer without other changes to the device or its labelling. The manufacturer has determined that this does not constitute a new version/model of the system, according to their documented procedures for assessing device changes (e.g. the safety profile, the performance of the system and the intended use are unchanged). Because the change in the component does not result in a new model/version of the system, the system UDI-DI and UDI-PI remain unchanged.

10 Updating the Quality System

Assuming that each company has already in place a validated traceability system, the additional requirements for the quality management system include:

- Identify who in the company has the responsibility to register the basic UDI-DI and the related UDIs;
- Verify if the current traceability system is compatible with the UDI labelling system;
- Verify if the current batch management system is compatible with the UDI, including software and hardware;

- Re-validate the traceability and batch management systems, where necessary;
- Update the technical documentation with the Basic UDI;
- Update the product information with the UDI;
- Informing the customers; and
- Update current procedures including responsibilities and accountability for maintaining the UDI information.

In addition, gas companies making medical devices available on the market as distributors (e.g. medical devices for administration of medical gases; medical gases used in homecare) shall verify that an UDI has been assigned by the respective manufacturers, taking into consideration the transition period, the deadlines for the implementation of the UDI for each risk class and the dates of implementation of the UDI-DI carrier on the packaging.

In the context of this activity they may apply a sampling method that is representative of the devices supplied.

11 References

Unless otherwise stated the latest edition shall apply.

[1] MDR

[2] http://www.imdrf.org/docs/imdrf/final/consultations/imdrf-cons-udi-system-n48-180712.pdf

[3] MDCG 2018-1 Draft guidance on BASIC UDI-DI and changes to UDI-DI – rev 2 Feb.2019

[4] MDCG 2019-1 MDCG guiding principles for issuing entities rules on Basic UDI-DI – Rev.0 Jan 2019

[5] MDCG 2018-3 Guidance on UDI for systems and procedure packs- Rev.0 Oct.2018

[6] MDCG 2018-4 Annex: UDI database Definitions/Descriptions and formats of the UDI core elements for systems or procedure packs – Rev.0 Oct. 2018

[7] MDCG 2019-5 Registration of legacy devices in EUDAMED rev.0 April 2019

[8] Draft Functional specifications for the European Database on Medical Devices (Eudamed) - First release (High(1)) to be audited - First draft consolidated version of functional specifications for Eudamed (version 4.1)

[9] https://ec.europa.eu/docsroom/documents/34264/attachments/1/translations/en/renditions/native

[10] MDCG 2018-2 Future EU medical device nomenclature - Description of requirements

Appendix 1 – Nomenclature

The European Commission has chosen the Italian nomenclature CND as the standardized European nomenclature to be used for regulatory purpose, in particular for registration of devices in the EUDAMED database.
Below are the CND codes available for the most common medical device gases and medical gas pipeline systems and accessories.

K020499	argon gas surgical devices - others
	Example: argon for plasma-coagulation
V0901	carbon dioxide
	Example: CO_2 for insufflation procedures
V0902	liquid nitrogen
	Example: N_2 for cryosurgery
V0903	gas mixture
	Example: CO_2 / O_2 mixtures for cellular culture
V0904	nitrous oxide
	Example: nitrous oxide for cryosurgery
V0999	fluid/gas for clinical/therapeutical use – others
	Example: ophthalmic gases
Z120309	medical/medicinal gas systems and relative accessories
	Example: Medical gas supply system for O_2, medical gas supply system for vacuum, line pressure regulator

For more information on the CND nomenclature, see MDCG 2018-2, Future EU medical device nomenclature - Description of requirements and CND translated list on the the Italian ministry of Health webpage
http://www.salute.gov.it/imgs/C_17_pagineAree_328_listaFile_itemName_21_file.xlsx