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

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Prepared by WG-15 Medical Equipment
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9.1.2	Unit of use UDI-DI declared not applicable; UDI-PI included more details for application flexibility
9.2	Clarified that bulk deliveries may occur with different types of shipping containers
9.1.2	Unit of use UDI-DI declared not applicable; UDI-PI included more details for application flexibility
9.4	Removed the concept of configurable device; Included possible different interpretation of UDI-DI and UDI-PI; removed not suitable examples, according with the new UDI-DI and UDI-PI interpretations.
11	Updated references

NOTE Technical changes from the previous edition are underlined

1 Introduction

On the 25th May 2017, the new European Regulation EU 2017/745 on Medical Devices, (MDR) came into force and replaced the Directive 93/42/EEC and its national transpositions [1][1]. It has come into full application on the 26th May 2021, but for certain legacy devices the transition period has been extended up to 2028 [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 updated in February 2024 with the new information available at that time [3,5, 7, 9, 10] It will be updated if significant changes to 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 Human Readable Interpretation ('HRI')

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

3.2.3 Issuing entity

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

3.2.4 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.

3.2.5 Model

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

3.2.6 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.

3.2.7 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.

3.2.8 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 EUDAMED and interaction with stakeholders can be represented in Figure 1:

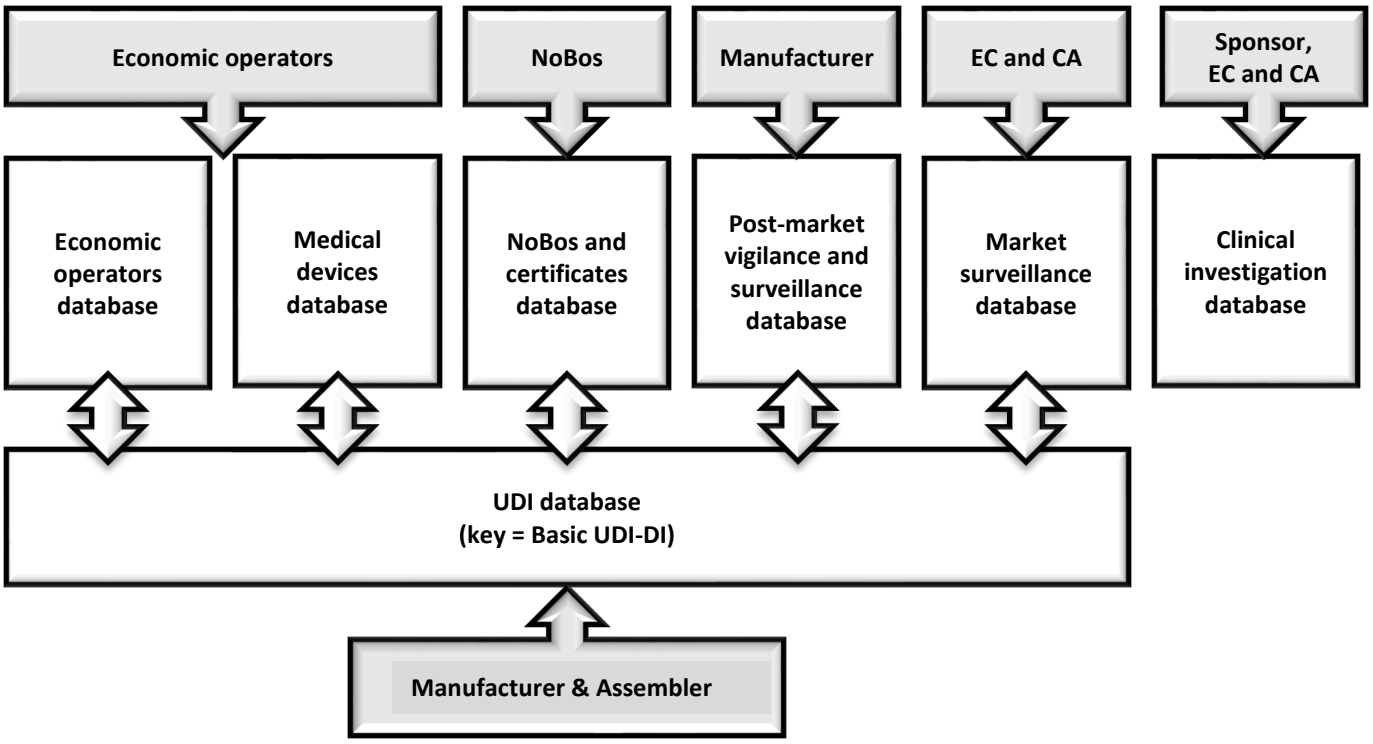

Figure 1 – EUDAMED structure

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 a 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.

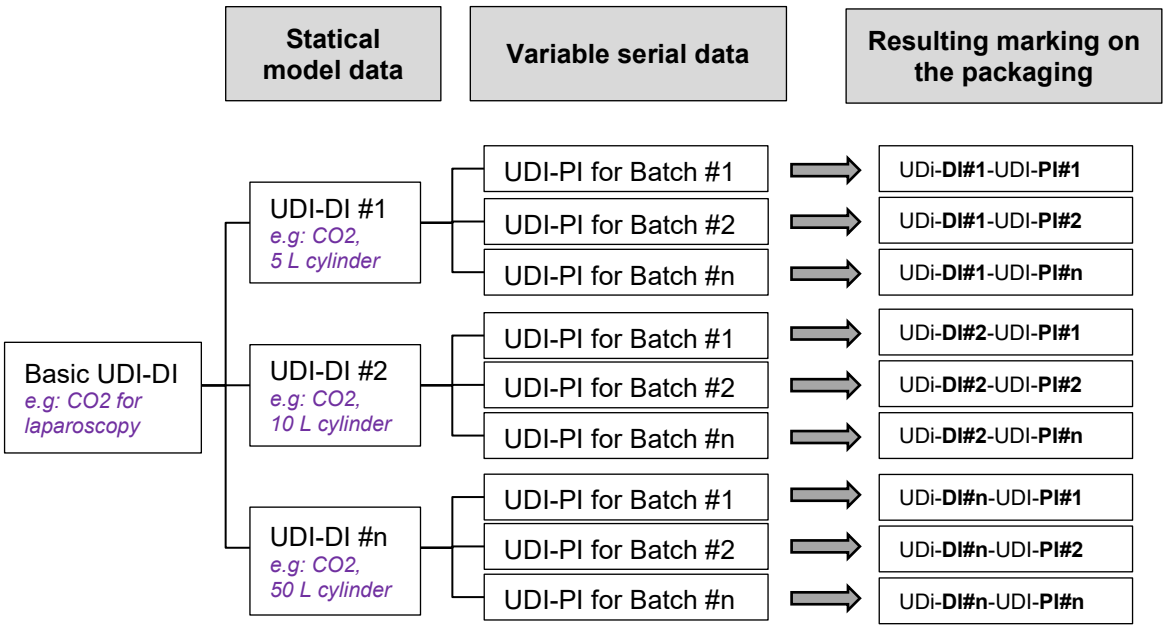

Figure 2 – UDI summary

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 [3]. 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 one of the following, as 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

For legacy devices with a valid certificate according to MDD the assignment of UDI codes is not required.

During the transition period, although not mandatory, a EUDAMED-DI can be assigned in analogue to the Basic UDI-DI. In this case it is automatically and fully generated by EUDAMED and it will start with the prefix “B” [7].

Instead of the UDI-DI, the EUDAMED ID can be assigned by the manufacturer.

MDR devices	Legacy devices	Example for Legacy device
Basic UDI-DI	EUDAMED-DI	B-XXXXXXXXXX
UDI-DI	EUDAMED -ID	XXXXXXXXXX

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 our industry is, 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 [1, 4] 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

The implementation dates defined by the European Commission for the placing of UDI-carriers on the label of MDR compliant medical devices are the following:

- Class III: 26th May 2021

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

If the MDR device, other than class I, is approved after the above dates then it shall immediately need to comply with the UDI-carrier requirement.

The requirement is not mandatory for legacy devices, however it may be applied before the MDR certificate is issued. The implementation of the UDI carrier is not considered as a major change.

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 it is not possible to place the UDI carrier on the device (gas), the UDI carrier is displayed on the gas package.

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 UDI-DI (UoU-DI)

The aim of the UoU-DI is to create traceability between the quantity of a device used or delivered and a single patient. For medical device gases this is not possible since the gas is administered to the patient by separate devices, therefore, no volume or mass of gas can be meaningfully allocated to an individual patient before its use, thus the UoU-DI is not applicable in the case of medical device gases.

c) UDI-DI on base package

A single UDI-DI shall be defined according to the variants identified by the manufacturer e.g. by cylinder size, valve outlet or specific label (language). The defined criteria shall be documented by the manufacturer.

d) UDI-PI

The UDI-PI shall contain as minimum information the production batch number. If other information is included in the UDI-PI (e.g. expiry date) then the defined criteria shall be documented by the manufacturer.

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 UDI-DI (UoU-DI)

The aim of the UoU-DI is to create traceability between the quantity of a device used or delivered and a single patient. For medical device gases this is not possible since the gas is administered to the patient

by separate devices, therefore, no volume or mass of gas can be meaningfully allocated to an individual patient before its use, thus the UoU-DI is not applicable in the case of medical device gases.

c) UDI-DI o base package

A single UDI-DI shall be defined according to the variants identified by the manufacturer e.g. by dewar size or specific label (language). The defined criteria shall be documented by the manufacturer.

d) UDI-PI

The UDI-PI shall contain as minimum information the production batch number. If other information is included in the UDI-PI (e.g. expiry date) then the defined criteria shall be documented by the manufacturer.

e) Shipping package

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

9.2 Applying UDI to bulk delivery of liquid gases

The bulk delivery refers to the transportation and delivery of large quantities of liquid gases in specialized containers or vessels (e.g. road tankers or mobile cryogenic vessels) to several customers.

The medical device gas in its liquid state is therefore delivered without primary package: the road tanker or mobile vessel used by the gas manufacturer are just means of delivering (shipping containers), while the containers where the gas is filled into remain at the customer site. This is a very special and unusual situation in the field of medical devices.

To address this very specific case, where the gas cannot carry by itself the UDI carrier, EIGA propose by convention to use one UDI-DI irrespective of the shipping containers and irrespective of the container at the customer site.

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

9.2.1 For bulk delivery of liquid medical device gases

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 UDI-DI (UoU-DI)

The aim of the UoU-DI is to create traceability between the quantity of a device used or delivered and a single patient. For medical device gases this is not possible since the gas is administered to the patient by separate devices, therefore, no volume or mass of gas can be meaningfully allocated to an individual patient before its use, thus the UoU-DI is not applicable in the case of medical device gases.

c) UDI-DI on base package

Since there is no base package in the case of bulk delivery of liquid medical device gases the UDI-DI carrier shall appear on the accompanying documents.

d) UDI-PI

The UDI-PI shall contain as minimum information the production batch number. If other information is included in the UDI-PI (e.g. expiry date) then the defined criteria shall be documented by the manufacturer.

The UDI-PI may be the same for several customers receiving the same production batch.

e) Shipping container

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.

9.3 Applying UDI to medical gas pipeline systems and similar installations

A basic UDI-DI has to be assigned to the medical gas pipeline systems as a whole, having the same group of components and the same intended purpose.

The UDI-DI could be defined in different ways, therefore the defined criteria shall be documented by the manufacturer.

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.

9.4 For medical gas pipeline systems

a) Basic UDI-DI

Pipeline systems for medical gases (all gases).

b) UDI-DI

Since there is no package the UDI-DI shall be on the label of the device itself, assigned as per manufacturer definition. Examples:

- One DI per single installation
- One DI per gas line

A new UDI-DI should be considered by the manufacturer if activities performed result in a change/modification in performance, safety and/or intended use, of the device. The manufacturer shall document the criteria for the change.

c) UDI-PI

The UDI-PI shall contain as minimum information the 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 installation. (Ref MDR Annex VI.B points 1, 6.4) [1].

Examples:

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

NOTE The manufacturer shall document where to affix the UDI label.

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 [9]:

- 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] *Regulation on medical devices:* (EU) 2017/745 (MDR) April 2017

[2] *Regulation amending Regulations 2017/745 and 2017/746 as regards the transitional provisions of certain medical devices and in vitro diagnostic mendical devices:* (EU) 2023/607 – March 2023

[3] MDCG 2018-1 *Guidance on BASIC UDI-DI and changes to UDI-DI* – Rev.4 April 2021

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

[5] MDCG 2018-3 *Guidance on UDI for systems and procedure packs* - Rev.1 June 2020

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

[7] MDCG 2019-5 *Registration of legacy devices in EUDAMED* - April 2019

[8] *Functional specifications for the European Database on Medical Devices (Eudamed) - to be audited (only for Minimum Viable Product (MVP) Legal Priority) - Consolidated version of functional specifications for EUDAMED* - version 7.2

[9] MDCG 2021-19 *Guidance note integration of the UDI within an organisation's quality management system* - July 2021

[10] MDCG 2022-7 *Q&A on the Unique Device Identification system under Regulation (EU) 2017/745 and Regulation (EU)* - May 2022

[11] MDCG 2018-2 *Future EU medical device nomenclature - Description of requirements* - March 2018

[12] *The EMDN – The nomenclature of use in EUDAMED* - January 2020

[13] *The CND nomenclature – Background and general principles* – January 2020

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.

V0905	Clinical / therapeutic application Argon
	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 EMDN nomenclature, see MDCG 2018-2[11], The EMDN – The nomenclature of use in EUDAMED[12]; The CND nomenclature – Background and general principles[13]