MedTech Europe
from diagnosis to cure

UDI System in the US and in the EU

Mapping of the differences

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Although both US and EU UDI system requirements are following the principles laid down in the IMDRF UDI guidance, there are a number of discrepancies between the two systems.
In this document MedTech Europe aims at providing a better clarity on the differences of the two UDI systems by mapping the alterations in the requirements for UDI labelling, as well as, in the UDI data submission requirements/ terminology.

Disclaimer: Please note that the content of this document represents MedTech Europe's current understanding of the differences which may change due to the currently formulating technical requirements of the future European medical devices database (Eudamed).

	Differences in labelling	EU	US
Rules for special cases/ Exemption	**1 -** Exemptions to UDI as required by IMDRF/UDI WG/N7FINAL:2013, Section 6.6 (a robust and transparent mechanism for evaluating and adjudicating requests for UDI exemptions in alternative placements of UDI-DI and UDI-PI) Is there a categorical exemption process / mechanism from the assignment or the placement of UDI?	There is no categorical exemption allowed by the MDR/IVDR for the assignment of UDI. There are a number of exceptions if particular circumstances are met.	Generally speaking, FDA allows for an exception or alternative solution (through FDA help desk) but there is no general exemption as such. *Ref:* 21 CFR 801.55
Rules for special cases/ Exception	**2 -** Location of UDI carrier – Exceptions I	Annex VI, Part C, 4.2. of MDR/IVDR *"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."*	No such exception but: UDI System, FAQ, Vol.1 of 20 Aug. 2014, Response to Question B3: *If there is no room for the UDI on the current label, can the labeler design a new label with just the UDI and place it on the package?*

			The final rule does not specify the type of label that is required to bear a UDI. It is up to the labeler to determine an appropriate method to apply the UDI to the device label. An add-on label, in some instances, may be appropriate. However, a UDI must be included on the device label and every device package. A7: *See:* 21 CFR 801.55 for the exception mechanism.
Rules for special cases/ Exception	**3 -** Location of UDI carrier – Exceptions II	Annex VI, Part C, 4.7. of MDR/IVDR *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.*	21 CFR 801.40 (a) […] *The UDI must be presented in two forms:* *(1) Easily readable plain-text, and* *(2) Automatic identification and data capture (AIDC) technology*
Rules for special cases/ Exception	**4 -** UDI Carrier – Exception I	Annex VI, Part C, 4.12 of MDR/IVDR *If the UDI carrier is readily readable, or in the case of AIDC scannable, through the device's packaging, the placing of the UDI carrier on the packaging shall not be required.*	No such exception
Rules for special cases/ Exception	**5 -** UDI Carrier – Exception II	Annex VI, Part C, 4.13. of MDR/IVDR *In the case of single finished devices made up of multiple parts that must be assembled before their first use it shall be sufficient to place the UDI carrier on only one part of each device.* (Annex VI, Part C, 3.6. of MDR/IVDR *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.)*	In the US, the components are considered to be medical devices (differences in the definition of the term medical device): *The label of every medical device shall bear a unique device identifier (UDI) that meets the requirements of Part 801 subpart B and part 830.* *Ref:* 21 CFR 801.20
Rules for special cases/ Exception	**6 -** Direct Marking	The EU does not except devices that are only cleaned between different patient use and single patient use. Annex VI, Part C, 4.10. of MDR:	Devices, that are only cleaned between different patient use and single patient use, do not need to be direct marked.

		"Devices that are reusable shall bear a UDI carrier on the device itself. *The UDI carrier for reusable devices that require cleaning, 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.* In the EU the reprocessed single-use devices are considered to be remanufactured and therefore the reprocessor is considered the manufacturer of the reprocessed device taking responsibility for traceability of the device. MDR Art. 17(2).	Ref: 21 CFR 801.45 and FDA UDI Guidance on Direct Marking of Devices Guidance (Nov 2017): C.1. How is "intended to be used more than once" defined for purposes of UDI direct marking? *For the purposes of the UDI direct marking requirements, under 21 CFR 801.45, "intended to be used more than once" means intended for repeated uses on or by different patients, e.g., where a device is cleared or approved and labeled for repeated uses on or by different patients. If the device is intended to be used more than once on or by the same patient, and not on or by multiple patients, then the device does not need to be directly marked with a UDI.* C.2.What does FDA consider "intended to be reprocessed" for the purposes of UDI direct marking? *For purposes of UDI direct marking requirements, we consider a device intended to be reprocessed if it is intended to undergo high-level disinfection and/or sterilization before each use or between uses. This means that devices that are only intended to be cleaned and/or to undergo lower levels of disinfection without subsequent high-level disinfection[1] or sterilization before each use or between uses are not required to be directly marked with a UDI under 21 CFR 801.45.* *Ref:* 21 CFR 801.45 *and* Unique Device Identification: Direct Marking of Devices Draft Guidance issued June 26, 2015
Rules for special cases/ Exception	**7 -** Direct Marking requirement	Annex VI. Part C 4.1. of MDR/IVDR: *The UDI carrier (AIDC and HRI representation of the UDI) shall be placed on the label or on the device itself and on all higher levels of device packaging.:* Annex VI. Part C 4.7. of MDR/IVDR:	21 CFR 801.45 *(c) Form of a UDI when provided as a direct marking. When a device must bear a UDI as a direct marking, the UDI may be provided through either or both of the following:* *(1) Easily readable plain-text;*

[1] For purposes of this guidance document, high-level disinfection is a lethal process utilizing a sterilant under less than sterilizing conditions. The process kills all forms of microbial life except for large numbers of bacterial spores.

		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. In the EU the exception applies that only the AIDC is required if there are significant space constraints (on any level of the label). Otherwise, the European approach seems to require both HRI and AIDC for Direct Marking. Annex VI Part 4.10 of MDR/IVDR: *Devices that are reusable shall bear a UDI carrier on the device itself. The UDI carrier for reusable devices that require cleaning, 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. The requirement of this Section shall not apply to devices in the following circumstances:* *(b) the device cannot be directly marked because it is not technologically feasible.*	*(2) Automatic identification and data capture (AIDC) technology, or any alternative technology, that will provide the UDI of the device on demand."* 21 CFR 801.45 *(c) Form of a UDI when provided as a direct marking. When a device must bear a UDI as a direct marking, the UDI may be provided through either or both of the following* *(1) Easily readable plain-text;* *(2) Automatic identification and data capture (AIDC) technology, or any alternative technology, that will provide the UDI of the device on demand."* In the US, Direct Marking UDI can be provided either one or both in AIDC and HRI format on the device itself.
Rules for special cases/ Exception	**8 -** Direct Marking Exception	Annex VI, Part C, 4.10. of MDR/IVDR *The requirement of this Section shall not apply to devices in the following circumstances:* *(a) any type of direct marking would interfere with the safety or performance of the device;* *(b) the device cannot be directly marked because it is not technologically feasible.* The exception in the US to allow a device that has been previously marked is NOT applicable in the EU.	21 CFR 801.45(d) & (e) *(d) Exceptions.* *The requirement of paragraph (a) of this section shall not apply to any device that meets any of the following criteria:* *(1) Any type of direct marking would interfere with the safety or effectiveness of the device;* *(2) The device cannot be directly marked because it is not technologically feasible;*

			(3) The device is a single-use device and is subjected to additional processing and manufacturing for the purpose of an additional single use. *(4) The device has been previously marked under paragraph (a) of this section.* *(e) Exception to be noted in design history file. A labeler that decides to make use of an exception under paragraph (d of this section) must document the basis of that decision in the design history file required by 820.30(j) of this chapter.* The labeller that decides to make use of an exception must document the basis of that decision in the design history file.
Rules for special cases/ Exemption	**9 -** "Existing inventory" exemption	The EU MDR/IVDR does not have this exemption and does not need such exemption since the UDI-requirement is implemented simultaneously with the MDR/IVDR. Therefore, the transition periods of the MDR/IVDR apply simultaneously to UDI. When products are certified to the EU MDR/IVDR, the requirements become effective, consistent with the timeline published in the regulations. For MDR: assigning and registering UDI by MDR Date of Application (26 May 2020) for all classes if Eudamed is launched until 26 March 2020; placing UDI carrier on the label: 26 May 2021 for Class III, 26 May 2023 for Class IIa and IIb, 26 May 2025 for Class I medical devices). For IVDs: assigning and registering UDI by IVDR Date of Application (26 May 2022) for all classes; placing UDI carrier on the label: 26 May 2023 for class D devices, 26 May 2025 for class B and class C devices 26 May 2027 for class A devices. (Legacy) Devices lawfully placed on the market before the MDR/IVDR Date of Application (26 May 2020/2022) may continue to be made available on the market or put into service latest until 27 May 2025 in case having a valid MDD/AIMDD/IVDD Certificate issued by a notified body.	21 CFR 801.30 (1) Exists for 3 years post the UDI implementation date.

		The only way to place MDD/AIMDD/IVDD compliant devices on the market after DoA is described in Article 120(3) of MDR/ Article 110(3) of IVDR (having valid NB certificate and provided that there are no significant changes in the design and intended purpose). CAMD FAQ on MDR transitional provisions *Q7: Are MDR compliant devices placed on the market according to Article 120(5) of MDR subject to the so-called "sell off" provision in Article 120(4) of MDR?* *No, the possibility of their being made available/put into service is not time-limited.*	
Rules for special cases/ Exception	**10 -** Single Used Device packaging exception	Annex VI, Part C, 4.3. of MDR/IVDR *"For single-use devices of class I and IIa for MDs and Class A and B for IVDs 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 individually packaged devices.* *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 of the individual device."* In the EU the condition is that the devices should be packaged and labelled individually. A differentiation between homecare and hospital use is hard to judge.	21 CFR 801.30 – Labeling Requirements for Unique Device Identification *"(a) In general. The following types of devices are excepted from the requirement of § 801.20; a device within one or more of the following exceptions is not required to bear a unique device identifier (UDI):* *[…]* *(3) Individual single-use devices, all of a single version or model, that are distributed together in a single device package, intended to be stored in that device package until removed for use, and which are not intended for individual commercial distribution.* ***This exception is not available for any implantable device.*** *The device package containing these individual devices is not excepted from the requirement of § 801.20, and must bear a UDI."*
Rules for special cases/ Exception	**11 -** "GMP-exempt" class I devices	No such concept/ exception exists in the EU	"GMP-exempt" class I devices are exempt from UDI labelling: 21 CFR 801.30 (a)(2) *"(2) A class I device that FDA has by regulation exempted from the good manufacturing practice*

			requirements of part 820 of this chapter, exclusive of any continuing requirement for recordkeeping under 820.180 and 820.198."
Format and Content of UDI	**12 -** UDI-PI for Class I devices	Annex VI, Part C, 4.4 of IVDR/MDR: *"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."* Clarification is needed whether UDI-PI in HRI is not required for Point of Sale either.	21 CFR 801.30 (d): *"The UDI of a class I device is not required to include a production identifier".* 21 CFR 801.40(d) *"A class I device that bears a Universal Product Code (UPC) on its label and device packages is deemed to meet all requirements of subpart B of this part. The UPC will serve as the unique device identifier required by § 801.20."* The US provides an exception specific to Class I retail Point of Sale which allows for the use of the UPC carrier which does not include the capability to capture the PI. In addition, the US provides a broader exception that Class I devices are not required to include a PI. The scope of the US exception is broader that the one in the EU where it is limited to "devices exclusively intended for retail".
Rules for special cases/ Exception	**13 -** Procedure Packs (should not be mixed up with IVD kit which is a device in its own right -so its components do not need to be labelled with UDI)	Annex VI, Part C, 6.3.2. of MDR *"Device contents of system or procedure packs shall bear a UDI carrier on their packaging or on the device itself.* *Exemptions:* *(a) individual single-use disposable devices, the uses of which are generally known to the persons by whom they are intended to be used, which are contained within a system or procedure pack, and which are not intended for individual use outside the context of the system or procedure pack, shall not be required to bear their own UDI carrier.*	21 CFR 801.30 - Labeling Requirements for Unique Device Identification *"(a) In general. The following types of devices are excepted from the requirement of § 801.20; a device within one or more of the following exceptions is not required to bear a unique device identifier (UDI):* *[…]* *(11) A device packaged within the immediate container of a combination product or convenience kit, provided that the label of the combination product or convenience kit bears a UDI."* FDA guidance document - Convenience Kits (draft, Jan 2016)

		(b) devices that are exempted from bearing a UDI carrier on the relevant level of packaging shall not be required to bear a UDI carrier when included within a system or procedure pack."	
Format and Content of UDI	**14 -** Splitting Barcodes	Annex VI, Part C, 4.6. of IVDR/MDR *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.*	UDI System: Form and Content of the UDI - Draft Guidance – July 26, 2016, IV.A. 2 *Due to space limitations or other reasons, the AIDC form of the UDI may be split into multiple segments. For example, one UDI may be presented in two linear bar codes:* *one bar code for the DI and another bar code for the PIs.* *These two bar codes should be proximally located to each other on the device label, device packages, and when required, on the device itself.* *Additionally, the DI bar code should precede the PI bar code.* *Ref:* Draft Guidance, Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI)*July 26, 2016.*
Format and Content of UDI	**15 -** RFID technology	Annex VI, Part C, 4.9. of IVDR/MDR *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.*	21 CFR 801.40 (c) *If the AIDC technology is not evident upon visual examination of the label or device package, the label or device package must disclose the presence of AIDC technology.* The US does not have this requirement. If the UDI is not visible to the human eye (RFID technology) the label or device package must disclose the presence of the alternate technology. It is up to the discretion of the labeller to determine how best to disclose the presence of the alternate technology that is not evident upon visual examination. *Ref:* Draft Guidance, Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI) *issued July 26, 2016.*

Format and Content of UDI	**16 -** UDI Carrier	Annex VI, Part C, 4.15. of MDR/IVDR *Barcode carriers that include both a UDI-DI and a UDI-PI may also include essential data for the device to operate or other data.*	**E. Order of the data represented in the UDI carrier** *For purposes of this draft guidance we define "UDI carrier" as the means to convey the UDI and any non-UDI elements by using easily readable plain-text and AIDC forms. In the UDI carrier, the UDI should precede any non-UDI elements. The easily readable plain-text form of the UDI should be ordered to specify the DI first, followed by the PIs. If there are any non-UDI elements in the UDI carrier, the non-UDI elements should follow the PIs that are part of the UDI.* *Ref:* Draft Guidance, Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI) *issued July 26, 2016.*
Format and Content of UDI	**17 -** UDI-PI manufacturing date requirements	MDR/IVDR Annex VI Part C 3.5. of MDR/IVDR *If a lot number, serial number, software identification or expiration 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.*	Whenever a device label includes a lot or batch number, a serial number, a manufacturing date, an expiration date, the UDI must include a production identifier segment that conveys such information unless exempt. *Ref:* 21 CFR 830.3
Placement of the UDI carrier	**18 -** Location of UDI Carrier and Direct Marking	Annex VI, Part C, 4.14. of IVDR/MDR *The UDI carrier shall be placed in a manner such that the AIDC can be accessed during normal operation or storage*.	**B.2. Question: Where is the UDI to be placed?** *The UDI is to be placed on the device label, device packages, and, if the device is intended to be used more than once and reprocessed between uses, on the device itself*. **B.3. Question: If there is no room for the UDI on the current label, can the labeler design a new label with just the UDI and place it on the package?** *The final rule does not specify the type of label that is required to bear a UDI. It is up to the labeler to determine an appropriate method to apply the UDI to the device label. An add-on label, in some instances, may be appropriate. However, a UDI must be included on the device label and every device package.*

			No specific guidance for the location of barcode other than the UDI is to be placed on the device label and device packages. *Ref:* Unique Device Identifier System: Frequently Asked Questions, Vol. 1 *issued August 20, 2014*
Placement of the UDI carrier	**19 -** Location of UDI carrier	Article 27(4) of MDR / Article 24(4) of IVDR *UDI carriers shall be placed on the label of the device and on all higher levels of packaging.* *Higher levels of packaging shall not be understood to include shipping containers.* Annex VI, Part C, 4.1. of MDR and IVDR *The UDI carrier (AIDC and HRI representation of the UDI) shall be placed on the label or on the device itself and on all higher levels of device packaging.* *Higher levels do not include shipping containers.* In the EU the definition of label covers also direct marking. *label' means the written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices*)	**21 §CFR 801.20** *(a) In general.* *(1) The label of every medical device shall bear a unique device identifier (UDI).* *(2) Every device package shall bear a UDI that meets the requirements of this subpart and part 830 of this chapter.*
Placement of the UDI carrier	**20 -** Software UDI	MDR/IVDR Annex VI Part C 3.5. of MDR/IVDR ***UDI-PI Requirement*** *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.* MDR/IVDR Annex VI Part C. 6.5.1. of MDR/ 6.1.2 of IVDR	FDA allows the UDI assigned to the physical medium on the software to be different from the UDI assigned to the software itself. US practice is to assign a manufacturing batch number to the package and the software version as the batch number on the about screen of the software itself. ***A.9. Question: Does software need to be labeled with a UDI?*** *The UDI Rule does not provide any special requirements for a device that contains software as a component of the device, but does require stand-alone medical software to be labeled with a UDI. All stand-alone software, whether packaged or unpackaged (e*

		UDI assignment criteria for software *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.* MDR/IVDR Annex VI Part C 6.5.4. of MDR/ of 6.2.4IVDR ***UDI placement criteria for software*** *where the software is delivered on a physical medium, e.g. 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.* UDI on the label and software must be identical in the EU. For the MDR/IVDR the UDI assigned to the system level software must match the UDI assigned to the physical medium containing the software and its packaging. • For distribution, packaged software is assigned a batch number to the physical CD and the package; this is different from the software version. Under MDR/IVDR requirements the software version needs to be included within the UDI carrier on the package and physical medium of the software and also the manufacturing batch number for the physical medium and the package within the software about screen UDI.	*.g., software downloaded from a website), must provide its UDI through either or both of the following: (1) An easily readable plain-text statement displayed whenever the software is started; (2) An easily readable plain-text statement displayed through a menu command (e.g., an "About..." menu command). Stand-alone software that is distributed in packaged form is subject to the same UDI labeling requirements as any other medical device -- the device label and device package must bear a UDI in plain-text and AIDC formats according to. Stand-alone software that is distributed in both packaged and not packaged form may be identified with the same DI. Stand-alone software that is not distributed in packaged form must convey the version number in its production identifier.* The UDI Rule does not provide any special requirements for a device that contains software as a component of the device but does require stand-alone medical software to be labelled with a UDI. Stand-alone software that is not distributed in packaged form must convey the version number in its production identifier *Ref:* Unique Device Identifier System: Frequently Asked Questions, Vol. 1*issued August 20, 2014, Question A.9*

	Differences in terminology / database content	EU	US
Definition	**21 -** Basic UDI-DI	MDCG 2018-1 EU Guidance on basic UDI-DI and changes to UDI-DI (March 2018) *"The Basic UDI-DI is the main key in the database and relevant documentation (e.g. certificates, declaration of conformity, technical documentation and summary of safety and clinical performance) to connect devices with same intended purpose, risk class and essential design and manufacturing characteristics.* *It is independent/separate from the packaging/labelling of the device and it does not appear on any trade item.* *Any Basic UDI-DI shall identify the devices (group) covered by that Basic UDI-DI in a unique manner."* Basic UDI-DI is a pure European concept. Basic UDI-DI groups all the UDI-DIs which refer to the same device (device variations covered by the same technical documentation and having the same risk class). It is established to be able to capture the 'regulatory' device for the purpose and usability of the Eudamed database. The Basic UDI-DI is an access key to the records in various modules of the Eudamed database (on clinicals, post-market surveillance, certificates etc.) The legal text of MDR/IVDR contains contradictions in the definition of the Basic UDI-DI which is resolved by the MDCG guidance document mentioned above. *"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."* The relation between the UDI-DI of an individual product and the Basic UDI-DI can be in 1:1 relation (which will be the case for most IVDs) – although the Basic UDI-DI should be different form UDI-DI and needs to be separately assigned.	No such a concept exists.

		However, according to the MDCG 2018-1 guidance on basic UDI-DI and changes to UDI-DI manufacturers have the possibility to group multiple UDI-DIs under one Basic UDI-DI if those are covered by the same technical documentation, have the same intended purpose and are in the same risk class. So devices having the same "essential design and manufacturing characteristics" can bear the same Basic UDI-DI. In Europe, UDI-DI identifies an individual device and Basic UDI-DI is the primary key for records in the Eudamed database.	
Definition	**22 -** Base package Primary UDI	In Europe, UDI-DI identifies an individual device.	Global Unique Device Identification Database (GUDID) – June 2014 *3.1.2 Device Identifier (DI) Record Primary DI: Each DI record will have a Primary DI, which is the primary key for the record. This is the DI of the lowest level of a medical device package containing a full UDI.* *The lowest packaging level is also the base package.*
Definition	**23 -** Unit of Use DI	Annex VI, Part C, 1. of MDR/IVDR 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."* The unit of use DI (*where a UDI is not labelled on the device at the level of its unit of use, a 'unit of use' DI shall be assigned so as to associate the use of a device with a patient*) is a UDI Core data element listed in Annex VI, Part B (4).	Global Unique Device Identification Database (GUDID) – June 2014: A virtual identifier assigned to an individual medical device when a UDI is not labeled on the individual device at the level of its unit of use. Its purpose is to associate the use of a device to/on a patient when a base package contains more than one device.
Definition	**24 -** "configurable devices"	Annex VI, Part C, 6.4. of MDR Configurable devices *"6.4.1. A UDI shall be assigned to the configurable device in its entirety and shall be called the configurable device UDI.* *6.4.2. The configurable device UDI-DI shall be assigned to groups of configurations, not per configuration within the group. A group of configurations is defined as the*	Not defined, requirement does not exist in the US due a difference in the definition of the term "device" which includes "component part". Also, in US any device that is available on its own must bear a UDI. *201 (h) FD&C Act*

		collection of possible configurations for a given device as described in the technical documentation. *6.4.3. A configurable device UDI-PI shall be assigned to each individual configurable device.* *6.4.4. The carrier of the configurable device UDI shall be placed on the assembly that is most unlikely to be exchanged during the lifetime of the system and shall be identified as the configurable device UDI.* *6.4.5. Each component that is considered a device and is commercially available on its own shall be assigned a separate UDI."* A UDI must be on each separately distributed component.	
Definition	**25 -** Procedure Pack	*MDR Article 2(10) Procedure Pack means a combination of products packaged together and placed on the market with the purpose of being used for a specific medical purpose*. See MDCG approved guidance: *MDCG 2018-3 Guidance on UDI for systems and procedure packs and MDCG 2018-4 Definitions/Descriptions and formats of the UDI core elements for systems or procedure packs*	Convenience Kit solely to apply to two or more different medical devices packaged together for the convenience of the user where they are intended to remain packaged together and not replaced, substituted, repackaged, sterilized, or otherwise processed or modified before the devices are used by an end user. *Ref:* Unique Device Identification: Convenience Kits *issued January 4, 2016.*
Definition	**26 -** Responsibility of UDI assignment and placement on the device	Responsibility of the manufacturer MDR Article 2(30) *'manufacturer' means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark;* MDCG approved guidance: *MDCG 2018-3* Definition of a System or Procedure Pack Producer *Article 22 of the Medical Device Regulation lays down certain obligations for natural or legal persons, that combine medical devices bearing a CE marking alone or together with other products which are not devices and are compliant with the respective legislation which apply to them, in order to place that combination on the market*	Responsibility of the labeller *Ref:* UDI Final Rule *24 September 2013.* *the labeler is the person who causes a label to be applied to a device, or who causes the label to be modified, with the intent that the device will be introduced into interstate commerce without any subsequent replacement or modification of the label; in most instances, the labeler would be the device manufacturer, but the labeler may be a specification developer, a single-use device reprocessor, a convenience kit assembler, a repackager, or a relabeler*

		as either a system or a procedure pack. That combination is intended to achieve a specific medical purpose. For the purpose of this guidance and operations related to EUDAMED, the natural or legal person referred to in Article 22(1), 22(2) and 22(3) of the Medical Device Regulation shall be called the "system or procedure pack producer".	
Definition	**27 -** UDI data entry responsibilities	The manufacturer shall be responsible for the initial submission and updates of the identifying information and other device data elements in the UDI database.	The labeller of a device provides the data elements for each version or model required to bear a UDI to the GUDID. *Ref:* 21 CFR 830.300
Database field	**28 -** Additional UDI Core data elements to submit into the central databases *(comparison)*	According to Annex VI, Part B of the MDR/IVDR (listing UDI Core data elements), the following additional data elements should be submitted in Eudamed compared to US FDA GUDID: • 2. Basic UDI-DI value • 6. Single registration number • 7. Name and address of the authorised representative • 9. Risk class • 13. Additional product data (optional) • 15. Additional trade names • 17. Maximum number of reuses • 21. Information labelled in accordance with Section 10.4.5. of Annex I (CMR / Endocrine disruptor substances) *(MDR only)* • 22. URL for additional information, such as electronic instructions for use (optional) • 23. Critical warnings or contra-indications (e.g. containing latex, MRI safety status, DEHP) *(MDR only)* • 24. Status of the Device Additional data elements to be provided by the manufacturer as part of UDI data registration, resulting from Part A of Annex VI: • 25. Reprocessed single-use device *(MDR only)*	Additional data elements comparing FDA GUDID Data Elements Reference Table (May 11, 2018) to Eudamed: • Previous DI Number • Previous DI Issuing Agency • DI Record Publish Date • Commercial Distribution End Date • Device Subject to Direct Marking (DM), but Exempt • DM DI Number • Package Type • Package Discontinue Date • Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P) • Kit • Combination Product • Device Exempt from Premarket Submission • Supplement Number • US FDA Listing Number • Product Code • Product Code Name • Production controlled by Donation Identification Number • Device labeled as "Not made with natural rubber latex"

		• 26. Specification as to whether the intended purpose of the device is other than a medical purpose (MDR Annex XVI) *(MDR only)* • 27. In the case of devices designed and manufactured by another legal or natural person as referred in Article 10(15), the name, address and contact details of that Natural/legal person	
Assigning UDI	**29 -** Changes that require a new UDI-DI Note: **Bold text shows the differences. The current EU list is subject to change and will be settled once the structure of the UDI/Eudamed database is finalised.**	MDR Annex VI, Part C.3.9 • 10. Name or trade (brand) name • 16. Labelled as single use • 18. Packaged as sterile • 19. Need for sterilisation before use • 23. Critical warnings or contra-indications (e.g. containing latex, MRI safety status, DEHP) MDR Annex VI, Part B (EU specific data elements triggering a new UDI-DI) • Issuing Agency • UDI-DI value • **1. Quantity per package configuration** • **2. Basic UDI-DI value** • **3. Type of UDI-PI** • **4. Unit of use UDI-DI** • Package DI value • **6. Single Registration Number of manufacturer** • **9. Risk classification** • 11. Device reference, article or catalogue number • 12. Clinical size *(MDR only)* • **17. Maximum number of reuses** MDR Annex VI, Part A (EU specific data elements triggering a new UDI-DI): • **25. Reprocessed single use device** *(MDR only)*	• Issuing Agency • Primary DI number • Brand name • Version or model number • Clinical size • **Kit status** • **Combination product status** • For single-use • Change to labelling for natural rubber latex or dry natural rubber • MRI safety status • Device packaged as sterile • Requires sterilization prior to use *Ref:* 21 CFR 830.50 *and* "GUDID Data Elements Reference Table (May 11, 2018)"

		• **26. Specification as to whether the intended purpose of the device is other than a medical purpose (MDR Annex XVI)** *(MDR only)* • **27. Name~~, address and contact details~~ of the legal or natural person (other than the manufacturer) that has designed or manufactured the device**	
Database fields	**30 -** Optional data fields	In the EU UDI database: Annex VI, Part B. UDI Core data elements • 13. Additional product description • 22. URL for additional information22. URL for additional information • Secondary DI	In the US GUDID: • Catalogue number • Commercial distribution end date • Secondary DI number • Name of Secondary DI Issuing agency • Previous DI Number • Name of Previous DI Issuing agency • Package Type (name or description of package) • Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P) • Device description • OTC (over the counter) • Storage and Handling Type
Database field	**31 -** Reprocessed Single Use	Annex VI, Part A, information relating to the device *2.6 Indication if the device is a reprocessed single use device*	Requirement to specify if device is single use, not if it is a reprocessed single use device. *Ref:* 21 CFR 830.310 *and* "GUDID Data Elements Reference Table (May 11, 2018)"
Database field	**32 -** Combination Product	Annex VI, Part A, information relating to the device *2.7 presence of a substance which, if used separately, may be considered to be a medicinal product and name of that substance*,	Requirement to specify a combination product but does not require the name of the substance *Ref:* 21 CFR 830.310 *? and* "GUDID Data Elements Reference Table (May 11, 2018)"
Database field	**33 -** Combination Product	Annex VI, Part A, information relating to the device *2.8 presence of a substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma and name of this substance*,	Requirement to specify a combination product but does not require the name of the substance *Ref:* 21 CFR 830.310 *? and* "GUDID Data Elements Reference Table (May 11, 2018)"

Database field	**34 -** Other Manufacturers	Annex VI, Part A, information relating to the device (introduced to be provided together with the UDI core data elements) *2.13 in the case of devices designed and manufactured by another legal or natural person: the name, address and contact details of that legal or natural person*	US UDI data entry is a requirement of the labeller not of the manufacturer
Database field	**35 -** Manufacturer name and address	Annex VI, Part B., UDI Core data elements *5. As indicated on the label*	Company name and address associated to the labeller DUNS number *Ref:* 21 CFR 830.310 *and* "GUDID Data Elements Reference Table (May 11, 2018)"
Database field	**36 -** Single Registration Number (SRN)	Annex VI, Part B. UDI Core data elements *6. Single Registration Number (SRN)* Number obtained after the manufacturer is validated the Competent Authority	No such concept exists in the US
Database field	**37 -** Medical Device Nomenclature	MDR Annex VI, Part B. UDI Core data elements *8. Nomenclature* Unknown for the moment, to be selected by the European Commission by the end of 1Q 2019 The nomenclature is one of the data elements under either Basic UDI-DI or under UDI-DI in Europe (still TBD), industry cannot assign Basic UDI-DI or UDI-DI before this policy decision is made and the granularity of the nomenclature is settled.	GMDN is required but does not trigger a new UDI-DI when it changes. *Ref:* 21 CFR 830.310 *and* "GUDID Data Elements Reference Table (May 11, 2018)"
Database field	**38 -** Name or trade name	Annex VI, Part B. UDI Core data elements 10. If applicable, name or trade name *The Proprietary/Trade/Brand name of the medical device model/version as used on the label. The EUDAMED system requires the language associated with that proprietary/brand/trade name if applicable.*	The Proprietary/Trade/Brand name of the medical device as used in device labelling or in the catalogue – required field *Ref:* 21 CFR 830.310 *and* "GUDID Data Elements Reference Table (May 11, 2018)"
Database field	**39 -** Device model, reference, or catalogue number	Annex VI, Part B. UDI Core data elements *11. If applicable, device model, reference, // or catalogue number*	FDA has Version/Model and Catalogue Number as two separate entries. The catalogue number field is not required. The version/model number is a required field. *Ref:* 21 CFR 830.310 *and* "GUDID Data Elements Reference Table (May 11, 2018)"

		The data element is separated into two fields in the EU UDI database, see European Commission UDI WG doc: https://ec.europa.eu/docsroom/documents/28669 *A) Name or, if applicable, device model that identifies the Basic UDI-DI Group in the technical documentation and/or certificate and declaration of conformity* *Description: Indication of the name or, if applicable, of the device model that identifies the Basic UDI-DI Group in the technical documentation and/or certificate and declaration of conformity.* *For clarifications related to the Basic UDI-DI, see dedicated guidance.* *B) Reference or catalogue number* *Description: The catalogue, reference, or product number found on the device label or accompanying packaging to identify a particular product.*	
Database field	**40 -** Clinical size	Annex VI, Part B. UDI Core data elements *12. If applicable, including volume, length, gauge, diameter* To be still decided how this field will be populated in the EU.	Size type (including volume, length, gauge, diameter), value, and unit of measure are conditionally reported. *Ref:* 21 CFR 830.310 *and* "GUDID Data Elements Reference Table (May 11, 2018)"
Database field	**41 -** Additional trade names	Annex VI, Part B. UDI Core data elements *15. If applicable, additional trade names*	Only one brand name allowed to be associated with a UDI-DI. *Ref:* 21 CFR 830.310 *and* "GUDID Data Elements Reference Table (May 11, 2018)"
Database field	**42 -** Reusable devices	Annex VI, Part B. UDI Core data elements *16. Labelled as single use Y/N* *17. If applicable, indicate the maximum number of reuses (as indicated on the label)*	No requirement to provide the maximum number of reuses for reusable devices. Only required to indicate if device is for single use or not. *Ref:* 21 CFR 830.310 *and* "GUDID Data Elements Reference Table (May 11, 2018)"
Database field	**43 -** Latex	Annex VI, Part B. UDI Core data elements *20. Indicate if latex is present*	Report to the GUDID if the device is required to be labelled as containing natural rubber latex or dry natural rubber; this includes packaging.

			If the device is labelled as "not made with natural rubber latex" the information can be optionally reported. *Ref:* 21 CFR 830.310 *and* GUDID Data Elements Reference Table (May 11, 2018)
Database field	**44 -** Substances which are carcinogenic, mutagenic or toxic to reproduction or endocrine-disrupting properties	Annex VI, Part B. UDI Core data elements *21. Indicate if device is labelled with an indication of these substances*.	Not required for UDI
Database field	**45 -** Direct marking	Direct marking will be a Y/N field in Eudamed. If direct marking UDI is different from the UDI on the packaging of the device, Eudamed is not able to capture it. When the direct mark UDI is different from the UDI on the packaging of the device, Eudamed is not able to capture the direct mark UDI and therefore no data can be retrieved about the device itself after when the packaging is no longer available.	The US GUDID indicates that the DM DI Number is different than the Primary DI Number. IF Device IS Packaged AND DM DI ≠ Primary DI on device label THEN select checkbox DM DI Different from Primary DI and Enter DM DI in DM DI field. Cases when the packaging UDI is different from the direct mark UDI: • device packaged in single and multiple packs • device provided both in sterile and also in non-sterile packaging • device provided in different sizes which are sold together
Database field	**46 -** Additional product information URL	Annex VI, Part B. UDI Core data elements *22. Optional to include URL for eIFU, etc.*	Not required for UDI. No input field available, but it can be included in the device description field according to the updated FDA guidance
Database field	**47 -** Status of the Device	Annex VI, Part B, UDI Core data elements *24. Status of the device* (differentiates between: *on the market, no longer placed on the market, recalled, field safety corrective action initiated*) - not including the date.	Commercial Distribution End Date Differentiates between “In commercial distribution” and “not in commercial distribution” *Ref:* 21 CFR 830.310 *and* "GUDID Data Elements Reference Table (May 11, 2018)"

Other	**48 -** Grace Period	No grace period provided for publication changes.	A published record to the GUDID has a 30-calendar day grace period to edit any attribute except for the publish date field. Ref: "GUDID Data Elements Reference Table (May 11, 2018)" FDA has opened up the GUDID to manufacturers to correct certain data – new data for record version.
Other	**49 -** Changes to data already submitted	MDR/IVDR Annex VI Part C 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.* Changes that affect the reported data elements, and does not require a new UDI-DI, shall be updated in the UDI database within 30 days of the change.	Updated information must be submitted no later than the date a device is first labelled with the changed information. If the information does not appear on the label of a device, the updated information must be submitted within 10 business days of the change. *Ref:* 21 CFR 830.330
Other	**50 -** Translations	MDR/IVDR Annex VI Part C 5.10 *The user interface of the UDI database shall be available in all official languages of the Union in accordance with article 53(2c). The use of free-text fields shall however be minimized in order to reduce translations.* MDCG 2018-7 Provisional considerations regarding language issues associated with the UDI database Optional fields remain only free-text fields. Value lists for Storage and handling conditions and Critical warnings+contra-indications, Clinical size are being implemented.	No translation of GUDID required
Other	**51 -** Data Review	MDR/IVDR Annex VI, Part C 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.*	No similar requirements in UDI rule
Other	**52 -** Implantable device UDI	MDR Annex VI, Part C 6.1.3. *The UDI of the implantable device shall be identifiable prior to implantation.*	No similar requirement called out in the US regulation. The device goes along with its label so information can be read from the label before transplantation.

Other	**53 -** Repackage/relabelling OEM device	MDR/IVDR Annex VI, Part C 3.10. *Manufacturers that repackage and/or relabel devices, with their own label shall retain a record of the original device manufacturer's UDI.* Original Equipment Manufacturer's (OEM) UDI	*The labeller is responsible for UDI requirements. The labeller is any person who causes a label to be applied to a device with the intent that the device will be commercially distributed or causing the label to be replaced/modified with the intent that the device will be commercially distributed. If you relabel a device that is required to bear a UDI you must assign a new device identifier to the device and keep a record showing the relationship of the prior DI to the new DI.* *Ref:* 21 CFR 830.60
Other	**54 -** Record retention	*Article 10 or MDR/IVDR* ***General obligations of manufacturers*** *8. Manufacturers shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, issued in accordance with Article 56, available for the competent authorities for a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market.* *Article 25 of MDR / Article 22 of IVDR* ***Identification within the supply chain*** *2.Economic operators shall be able to identify the following to the competent authority, for the period referred to in Article 10(8):* *(a) any economic operator to whom they have directly supplied a device;* *(b) any economic operator who has directly supplied them with a device;* *(c) any health institution or healthcare professional to which they have directly supplied a device.* *Article 27*	*Each labeller shall retain, and submit to FDA upon specific request, records showing all UDIs used to identify devices that must bear a UDI on their label, and the particular version or model associated with each device identifier. These records must be retained for 3 years from the date the labeller ceases to market the version or model.* *Ref:* 21 CFR 830.360 Retention of the UDI related information, not the regulatory information as mentioned by the EU law.

		Unique Device Identification system *[…]* *8.Economic operators shall store and keep, preferably by electronic means, the UDI of the devices which they have supplied or with which they have been supplied, if those devices belong to:* *— class III implantable devices;* *— the devices, categories or groups of devices determined by a measure referred to in point (a) of paragraph 11.* *[…]* *11.The Commission may, by means of implementing acts, specify the detailed arrangements and the procedural aspects for the UDI system with a view to ensuring its harmonised application …*	