MDCG 2021-10 - The status of Appendixes E-I of IMDRF N48 under the EU regulatory framework for medical devices

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This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

The MDCG hereby endorses the principles laid out under Appendixes E - I of the IMDRF N48 guidance document, as published on 21 March 2019 on the IMDRF website.

For ease of readability, this document intends to provide clarifications as to how certain principles and examples outlined in N48 Appendixes E-I apply under the MDR/IVDR. The examples provided within the Appendixes are for informative purposes and should not be interpreted as the sole manner for complying with UDI obligations.

It is recommended that these documents are always read in conjunction with Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR) and to take into consideration the respective issuing entity rules.

Certain principles and terminology set out within the IMDRF N48 Appendices are not applicable under the MDR/IVDR. The following comparison table explains the applicable MDR/IVDR principles and terminology that should be applied for compliance and is non-exhaustive in its nature. Please note that 'X' in the table below indicates that this IMDRF principle/terminology is not applicable under either the MDR and/or IVDR.

IMDRF Principle/Terminology	MDR Principle/Terminology	IVDR Principle/Terminology
UDI assignment for devices in packages	MDR allows for devices in packages to bear their own UDI.	IVDR allows for individual devices in packages to bear their own UDI.
Non-IVD kit	Procedure pack as defined by Article 2(10)	X
Customizable	Configuration	Configuration
'hygiene and disinfection'	an intended medical purpose has been claimed by the manufacturer for a device that is used for hygiene and disinfection	X
IVD kit	X	Kit per the IVDR definition
System UDI	'Configurable device UDI' according to Annex VI part C 6.4.	X
'Software as a Medical Device (SaMD)	Medical Device Software in accordance with MDCG 2019-11	Medical Device Software in accordance with MDCG 2019-11
UDI assignment for kits	MDR exempts separately distributed Class I single use devices as not requiring labelling at unit of use level. – Annex VI, Part C, 4.3	X
UDI registration in	The manufacturer shall provide to	The manufacturer shall provide

EUDAMED	the UDI database the UDI-DI. – Annex VI, Part B.	to the UDI database the UDI-DI. – Annex VI, Part B.
Appendix I	Examples provided under this Appendix are best practice approaches to deal with UDI for software. In the EU, the creation of a Basic UDI-DI (which may serves as the DI for the software regardless how the software is made available) must be considered when deciding which manner the manufacturer will choose to comply with the UDI labelling requirements. The MDR does not make obligatory that the different ways of making available software will be subject to a mandatory UDI-DI trigger. This however, should not be misunderstood as being non-applicable, in particular if having different UDI-DIs could avoid misidentification on the market.	Examples provided under this Appendix are best practice approaches to deal with UDI for software. In the EU, the creation of a Basic UDI-DI (which may serves as the DI for the software regardless how the software is made available) must be considered when deciding which manner the manufacturer will choose to comply with the UDI labelling requirements. The IVDR does not make obligatory that the different ways of making available software will be subject to a mandatory UDI-DI trigger. This however, should not be misunderstood as being non-applicable, in particular if having different UDI-DIs could avoid misidentification on the market.
Software PI (lot/batch)	Software PI (software version) software identification and manufacturing or expiry date or both types of date. Software identification may include 'version model'	Software PI (software version) software identification and manufacturing or expiry date or both types of date. Software identification may include 'version model'
Software delivered on a physical medium	MDR lays out that "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. – Annex VI, Part C, 6.5.4(a)	MDR lays out that "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. – Annex VI, Part C, 6.2.4(a)
UDI on different levels of packaging	EU MDR requires all levels of packaging to have unique UDIs. – Annex VI, Part C, 3.1	EU IVDR requires all levels of packaging to have unique UDIs. – Annex VI, Part C, 3.1