MDCG 2018-3 Rev.1

Guidance on UDI for systems and procedure packs

June 2020

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MDCG 2018-3 Rev 1 changes	
Section 3.2	Introduction of Example 2, new

1. Scope

This guidance should be read in conjunction with the Guidance on "Basic UDI-DI and changes to UDI-DI"[1] and the Guidance on "UDI database. Definitions, descriptions and formats of the UDI core elements"[2]. The guidance is not intended to be exhaustive in relation to all UDI obligations associated with systems and procedure packs. The scope of this guidance is therefore limited to the aspects specifically addressed below. For UDI-related aspects that are not specifically mentioned in this guidance, the reader should make reference to the relevant provisions of Medical Device Regulation (EU) 2017/745 (MDR).

2. Definitions

In accordance with Article 2 of the MDR,

‘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;

‘system’ means a combination of products, either packaged together or not, which are intended to be inter- connected or combined to achieve a specific medical purpose;

“Specific medical purposes” are defined in Article 2(1) of the MDR.

Examples of procedure packs are first aid kits, orthodontic procedure packs and skin traction kits.

Examples of systems are x-ray systems.

3. Principles of Article 22

3.1 Definition of a System or Procedure Pack Producer

[1] Guidance MDCG 2018-1 v3
[2] Guidance UDIWG 2018-1

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 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".

3.2 Exemption with regard to "system or procedure pack producer"

Based on a request of a client or hospital, a natural or legal person in the supply chain may make available together different products, including CE marked devices, which are – in that entire combination – neither placed on the market by that natural or legal person, nor intended by that natural or legal person to be used together for a specific medical purpose. Devices made available in the described manner are not considered as systems or procedure packs in accordance with the relevant definitions provided in Article 2 of the MDR. In this case, that natural or legal person is not regarded to be a system or procedure pack producer in accordance with Article 22.1, and is considered to be a distributor as per Article 2(34) of the MDR. It is to be noted that an importer may also make available devices to a client or hospital, in such manner.

Example 1: a distributor supplies, upon request of a client, in one shipment, sterile tweezers, a sterile needle and surgery gloves.

Example 2: Multi-device surgical sets comprised of individual devices delivered in trays for replenishment and sterilization for the request and for convenience of the healthcare provider and the healthcare system.

Under the conditions set in Article 22(4), systems and procedure packs are to be treated as devices in their own right and the related natural or legal persons shall assume the obligations incumbent on manufacturers. This specific scenario is out of the scope of the present guidance. Manufacturers of such devices shall refer to general guidance on UDI which is available on the DG GROW website[3].

[3] Guidance adopted by MDCG is available at https://ec.europa.eu/health/md_sector/new_regulations/guidance_en
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4. Registration of systems and procedure packs

The system or procedure pack producer shall apply for registration as a system or procedure pack producer and obtain an SRN.

Systems and procedure packs shall undergo a UDI registration, as described in Article 29(2) of the MDR. Before placing on the market a system or procedure pack pursuant to Article 22(1) and (3), that is not a custom-made device, the system or procedure pack producer shall assign to the system or procedure pack, in compliance with the rules of the issuing entity, a Basic UDI-DI and shall provide it to the UDI database together with the other core data elements referred to in Part B of Annex VI related to that system or procedure pack.

The UDI data elements applicable for systems and procedure packs are listed in the Annex to this guidance.

5. Specific UDI rules for systems and procedure packs

The Basic UDI-DI shall identify systems or procedure packs having the same group of components and the same intended purpose[4], regardless of the original components manufacturers.

System and procedure packs shall be assigned and bear their own UDI (including both UDI-DI and UDI-PI), in accordance with Annex VI, Part C, points 3.7 and 6.3.1. of the MDR

[4] This is to prevent that two systems or procedure packs with the same intended purpose, but having one or more components coming from different manufacturers, would need to be assigned two different Basic UDI-DIs.