The European Association
Medical Devices - Notified Bodies

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Team-NB Position Paper

on Documentation Requirements for Drug Device Combination Products

Falling in the Scope of Article 117 of MDR 2017/745.

Topic 1: Requirements on the submission file´s documentation (structure)

Each Notified Body is a separate, non-governmental organization and thus offers its own specific organizational setup. This organizational setup includes specific processes and specific interfaces on client interaction.

In consideration of this organizational setup of Notified Bodies, the requirements on the submission file format should only focus on general documentation related requirements, i.e. the structure and contents as well as the format related to the documentation submitted. The way of documentation submission to the respective Notified Body, the way of documentation handling, storage and archiving at the respective Notified Body are out of scope.

According to the second subparagraph of Article 117 (Regulation (EU) 2017/745 on medical devices (MDR)), the opinion issued by a notified body applies to "the conformity of the device part with the **relevant general safety and performance requirements set out in Annex I (GSPRs)** to that Regulation" ("that Regulation" being the MDR).

For medical devices being solely governed by the MDR, the documentation requirements related to the GSPRs are described in Annex II Technical Documentation (MDR, Annex II; in specific section 4). These documentation requirements should also be considered for the documentation of the device part.

A) Structure and content of the submission file of the device part

I. Contains a ***description of the device part*** covering

a. a general description of the device part including its intended purpose and intended users

b. the intended patient population and medical conditions to be diagnosed, treated and/or monitored and other considerations such as patient selection criteria, indications, contra-indications, warnings (for the integral product/ single integral product)

c. principles of operation of the device part and its mode of action, scientifically demonstrated if necessary

d. a description of the accessories for a device part, other devices and other products that are not devices, which are intended to be used in combination with it

e. a general description of the device part´s key functional elements, e.g. its parts/components (including software if appropriate), its formulation, its composition, its functionality and, where relevant, its qualitative and quantitative composition. Where appropriate, this shall include labelled pictorial representations (e.g. diagrams, photographs, and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams

f. a description of the raw materials incorporated into the device part´s key functional elements and those making either direct contact with the human body or indirect contact with the body, e.g., during extracorporeal circulation of body fluids;

g. technical specifications, such as features, dimensions and performance attributes, of the device part and any variants/configurations and accessories that would typically appear in the product specification (of the integral product/ single integral product) made available to the user, for example in brochures, catalogues and similar publications

II. Contains the ***instructions for use / product insert / package insert*** of the integral product/single integral product

III. Contains the ***documentation of the GSPRs*** covering a. a listing of the GSPRs

b. an identification of requirements that apply to the device part and an explanation as to why others do not apply

c. a summary of method(s) used to demonstrate conformity with each applicable GSPR and a summary of the results demonstrating the conformity

d. details on the method(s) adopted to meet the applicable GSPR (e.g. raw data, original test reports) including a justification, verification and validation of the method(s) adopted to meet the applicable GSPR

e. the identification of the harmonised standards, common specifications or other solutions applied to meet the applicable requirements

f. the precise identity of the controlled documents offering evidence of conformity; if the controlled documents offering evidence of conformity are included in any kind of summary documentation: the precise cross-reference to the location of such evidence.

B) Format of the device part´s submission file (including each document submitted)

1. Fully legible (including pictures, signatures etc)
2. Readily and searchable
3. Without any file/document access protection
4. Offering the structure and contents as described in section A) above with clear identification of the contents covered (e.g. via bookmarks, hyperlinks)
5. Offering unambiguous file and document identification (name, number, date, revision number etc.)

Topic 2: Role of the Notified Body in the assessment of the conformity of the device part with the relevant general safety and performance requirements (GSPRs) set out in Annex I

According to the second subparagraph of Article 117 (Regulation (EU) 2017/745 on medical devices (MDR)), the opinion issued by a notified body is "on the **conformity of the device part** with the **relevant general safety and performance requirements set out in Annex I (GSPRs)** to that Regulation" ("that Regulation" is MDR).

Based on this requirement, the respective **Notified Body in general sets the assessment focus on the device part.**

In case of GSPRs that do not only focus on the device part, but also on the device part´s interoperability and compatibility with other devices, products or substances (e.g. GSPRs 10.3 and 14.5), the respective Notified Body considers the influence of the other device, product or substance on the device part to be assessed (impact assessment). In the context of Article 117, such substance is the medicinal product that is part of the integral product / the single integral product – the respective Notified Body should assess if the medicinal product has any impact on the safety and performance of the device part.

This aspect of impact assessment also applies to specific manufacturing technologies, like e.g. sterilisation (GSPR 11.4); the Notified Body should assess if the respective technology/method applied has any impact on the safety and performance of the device part.

In contrast to the Notified Body**, the authority (European Medicines Agency (EMA) and/or National Competent Authorities (NCAs))** being responsible for the assessment of the marketing authorization dossier **sets the assessment focus on the medicinal product part.**

In consequence, any impact assessments performed by the EMA/NCAs focus on the effect of any product, device, substance and/or manufacturing technology on the medicinal product part.

The EMA/NCAs finally utilize the opinion issued by the Notified Body to have oversight on both assessment views – the device related one from the Notified body and the medicinal product one from the EMA/NCAs – and to decide on the conformity of the integral product / the single integral product according to the requirements of Directive 2001/83/EC relating to medicinal products for human use.