ZVEI:
Die Elektroindustrie

Guideline

Combining Medical Devices

(Guideline on article 12 of the MDD)

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German Electrical and Electronic Manufacturers' Association

Motivation

Medical devices are frequently put together for combined use in the form of a system[i]. However, operators and users – and manufacturers too – may be unclear on whether and when it is lawful to combine and use medical devices in this manner.

As manufacturers, operators and users face liability issues following the placement on the market and, more importantly, the operation of medical devices in combination, operators and users commonly require suppliers or the manufacturers of medical devices to provide statements declaring the mutual compatibility of medical devices, in most cases in a "declaration of conformity to article 12" of the Medical Devices Directive.

The situation is actually much more complex because different regulations apply depending on how the devices are interconnected and placed on the market.

This document has therefore been drawn up to clarify the regulatory requirements and to provide the necessary level of transparency to ensure that medical devices used in combination are in compliance with applicable laws.

Regulatory basis

European medical device legislation (Medical Devices Directive 93/42/EEC, "MDD") and its implementation in German law in the Medical Devices Act (*Medizinproduktegesetz*, MPG) propose two processes for the placement on the market of combined medical devices. These processes are based on different requirements and procedures:

Procedure based on article 11 of Council Directive 93/42/EEC

Article 11 of Council Directive 93/42/EEC sets out the conformity assessment procedures a medical device manufacturer must undergo before placing a medical device on the market in order to qualify for CE marking (implemented in sections 6 and 7 of the German Medical Devices Act and in the Ordinance on Medical Devices (MPV), section 7 in particular). A major component of a conformity assessment procedure is proof of compliance with the essential requirements set out in Annex I of the MDD.

A conformity assessment procedure cannot be conducted only for individual medical devices but must also be conducted for interconnected medical devices ("system", "procedure pack", "combination of medical devices") and include, for example, the use of a medical device in combination with accessories and other products[i]. Item 9.1 of the Essential Requirements set out in Annex I of the MDD merits special attention: *"If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection*

system, must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use."

However, systems in the medical device sector in particular are frequently not sold as a procedure pack; rather, one or more devices are combined by the operator or user with already existing products or products purchased at a later date. Operators and users therefore have to know whether the combination they want to use complies with laws and regulations.

Manufacturers can provide information on the lawfulness of a medical device interconnected with accessories or other medical devices by specifying the particular products included in the conformity assessment procedure for the system (standard case), or by describing permissible interconnections with other products by way of special product requirements (e.g. for standardized accessories). This information can be provided in the instructions for use for the main device or in a separate document.

Conformity assessment procedures in accordance with article 11 of the MDD can only be applied by medical device manufacturers who are registered as manufacturers with the competent authority and (depending on the risk category of their products) possess a valid EC certificate and are thus monitored by their Notified Body. The conformity assessment procedure concludes with the issuance of a declaration of conformity.

Given the considerable effort involved in demonstrating an entire system's compliance with the Essential Requirements, the procedure just described applies in practice only to the manufacturer's own medical devices.

Procedure based on article 12 of Council Directive 93/42/EEC

The procedure in accordance with article 12 of the MDD (implemented via section 10 of the German Medical Devices Act [MPG]) is a simplified special procedure for "systems and procedure packs" (and sterilisation) and applies to "system assemblers" who need not necessarily be medical device manufacturers themselves (they might be distributors, for example).

In most cases, products put together to give a system or procedure pack in accordance with article 12 of the MDD are from different manufacturers.

Application of article 12 of the MDD demands compliance with certain requirements, however, including the following

- all the products in a system or procedure pack must already have been granted CE marking as per the MDD, and

- the products must be put together in accordance with their intended purposes and in compliance with the restrictions on use proposed by the manufacturer, and

- placed on the market in the form of a system or procedure pack.

Moreover, the natural or legal entity involved in putting together and packaging the system or procedure pack must issue a statement confirming that they have

- verified the mutual compatibility of the products in line with the information provided by the manufacturers and performed the activities in accordance with the instructions;

- packaged the system or procedure pack and provided appropriate information for users, including the pertinent instructions of the manufacturers;

- provided suitable internal oversight and control over all these activities.

If a single one of these conditions has not been met, e.g. if a system or procedure pack contains products that do not bear CE marking in accordance with the MDD or if the combination of products is not compatible with their original intended purpose, the simplified procedure in accordance with article 12 of the MDD cannot be applied and a conformity assessment procedure as per article 11 must be used instead.

Another important criterion for application of article 12 of the MDD is that the system needs to be placed on the market as a complete unit; article 12 of the MDD does not cover subsequent combination with products that the operator already owns or purchases at a later date.

Anyone who places a medical device combination on the market as per article 12 of the MDD is required to register with the competent authority as the responsible party and also register the products placed on the market; unlike with article 11 of the MDD, these responsibilities are not limited to manufacturers. Registration with the competent authority must take place prior to initiation of the activity, and verification of compliance with the requirements of article 12 of the MDD and the issuance of the declaration as per article 12 of the MDD must take place before the system is placed on the market. The declaration must be retained for at least five years (or at least 15 years for implantable systems).

Assembly of a combination of medical devices by operators or users

When operators or users combine already marketed medical devices strictly for use in their own facility, section 4 (4) of the Medical Devices Operator Regulation (*Medizinprodukte-Betreiberverordnung*) applies. In this scenario, the operator rather than the system manufacturer has the responsibilities set out in

article 12 (2) of the MDD, but does not have to issue an article 12 declaration. If the operator or user does not comply with the limitations as per section 4 (4) of the Medical Devices Operator Regulation, for example by using the system for a purpose other than intended or by combining it with products that do not have CE marking, then the operator/user ultimately assumes the system manufacturer's responsibility for "in-house production" of a system as per article 12 (2) in conjunction with article 11 of the MDD. The Medical Devices Directive does not stipulate requirements for any such in-house production, since it only governs the placement on the market and subsequent putting into service of medical devices; however, section 12 of the German Medical Devices Act (§ 12 MPG) does stipulate criteria for the putting into service and operation of products or systems produced in-house. These criteria essentially correspond to the requirements for the manufacture and placement on the market of bespoke models and are described in detail in section 7 (9) of the Ordinance on Medical Devices (MPV). In particular, the operator or user must draw up technical documentation and issue a declaration that the relevant Essential Requirements set out in Annex I of the MDD are met – ultimately, it means that the operator or user must undergo the same conformity procedure as a manufacturer, apart from obtaining CE marking. The issuer of this declaration thus assumes liability for the performance and safety of the in-house product. The declaration must be retained for at least five years (or 15 years for implantable systems). The party responsible for an in-house product is not obliged to notify the competent authority provided the product is not "dispensed to others" (e.g. to another hospital).

Summary

The commonly requested application of article 12 of the MDD is permissible only if all of the criteria stipulated in article 12 of the MDD are met and the typically extensive procedure for verification of the mutual compatibility of the combined devices and their use for their specific individually intended purpose has been completed. A declaration pursuant to article 12 of the MDD can therefore only be issued if this verification procedure has been completed and documented and the system assembler has notified the competent authority as the responsible person and notified the authority of the use of the devices. The declaration and notification must take place before the system is placed on the market. Infringement of article 12 of the MDD is punishable by law. Post-hoc application of article 12 of the MDD to devices already owned by the operator or user is not allowed.

Alternatively, the manufacturer can conduct a conformity assessment procedure for a system of devices in accordance with article 11 of the MDD, which covers the potential combinations with other devices, and issue a declaration of conformity for the system. The permissibility of potential combinations can be described in the instructions for use of the devices involved or in a separate document issued by the responsible manufacturer. The above also applies to the identical devices specified therein which are already in the operator's or user's possession or are purchased at a later date. The application of a conformity procedure to a system of devices is generally only an option for a manufacturer's own devices, as the details required for a conformity assessment procedure are not usually available for products from other manufacturers. Moreover, without a contractual agreement with the other device manufacturer, it is not possible to ensure that alterations to the other product will be noticed and addressed in an update to the conformity procedure for the system.

If combinations are self-assembled by an operator or user without any reference to appropriate information in the instructions for use or to an appropriate statement by the responsible manufacturer, the system is an in-house product. In this instance, the operator or user is responsible for the performance and safety of the assembled combination and will also be held liable for it. Before putting the combination into service for the first time, the operator or user must demonstrate and document the combination's safety and permissibility and issue a declaration as per section 7 (9) of the MPV. This also applies if the operator or user commissioned a third party to assemble the combination on the operator or user's behalf. The declaration must be retained and presented to the competent authority upon request.

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[i] The terms “system”, “procedure pack” and “medical device combination” are not defined in the MDD, but article 12 of the MDD uses the terms “system” and “procedure pack.”

Definitions of “system” and “procedure pack” in the MDR (Medical Device Regulation – (EU) 2017/745)
article 2: Definitions
(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;
(11) "system" means a combination of products, either packaged together or not, which are intended to be interconnected or combined to achieve a specific medical purpose;