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Medical Devices – What's new?

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The updated Blue Guide on the implementation of EU product rules 2022 ("Blue Guide") has been released June 2022

On June 29th, 2022 the European Commission issued the updated and revised Blue Guide on the implementation of EU product rules 2022 ("Blue Guide"). The Blue Guide is a non-binding instrument, which was first published in 2000 and serves as an interpretative tool for the regulation of a wide range of products covered by European Union harmonization legislation, such as:

- Medical devices;
- Radio Equipment;
- Electric and electronic equipment;
- Toys;
- Machinery;
- Simple pressure vessels;
- Personal Protective Equipment ("PPE");
- Household appliances.

The document had already been updated twice in the past, in 2014 and 2016 respectively. The recent 2022 revision reflects recent changes in EU legislation, and, in particular, the provisions of the recently adopted Regulation (EU) 2019/1020 on market surveillance and compliance of products ("Regulation (EU) 2019/1020"). The new guidance introduced refers – among others – to a) the notion of placing on the market (including placing on the market in the context of distance and online sales), b) repairs and modifications to products and c) software.

❖ Placing on the market

A new section regarding making available and placing on the market in case of distance and online sales is added, which incorporates the guidance included in the Regulation (EU) 2019/1020 concerning when a product sold online or through distance sales is deemed to be targeted at end users in the European Union.

This section also provides examples regarding when the actual placing on the market for products sold online or through other means of distance sales is considered to take place depending on the chosen distribution chain.

More specifically, according to the new guidance:

- Products outside the EU, which can be bought directly by end users in the EU online are considered to be placed on the market at the moment an order has been placed and confirmed;

- Products offered online to end users in the European Union, which are first transferred to fulfillment service providers located in the EU, are deemed to be placed on the market at the time they are released for free circulation.

It is further provided that when products are sold online CE marking and any required warnings should be indicated on the website.

❖ Repairs and modifications to products

New guidance is added regarding when a repair or modification to a product is considered to be a "substantial modification", in which case the product is considered as a "new" product and needs to undergo a new conformity assessment procedure, update its technical documentation and draw-up an EU declaration of conformity.

In order to determine when a modification is considered "substantial", a three-step test is added, according to which a repaired or modified product is considered to be "new" when: i. its original performance, purpose or type is modified without being foreseen in the initial assessment; ii. the nature of the hazard has changed or the level of risk has increased in relation to the relevant EU product rules; iii. the product has been made available or put into service.

❖ Software

The updated Blue Guide provides that manufacturers have an obligation to "foresee the risks" of software integrated into a product at the time of its placing on the market and explains that the notions of "cyber risk" and "risk related to the loss of connectivity of devices" should be taken into account when assessing the overall product safety of a product.

A three-step test is also introduced for assessing when a software update is considered as a "substantial modification".

MDCG 2022-13 Designation, re-assessment and notification of conformity assessment bodies and notified bodies August 2022

This document aims to provide guidance to the authorities responsible for notified bodies and joint assessment teams ("JATs") when conducting: i. assessments of conformity assessments bodies ("CABs") that apply for designation as a notified body ("NB") in the field of medical devices and/or in vitro diagnostic medical devices, and ii. re-assessments of NBs. Furthermore, this guide is intended to bring consistency and to align the working practices of the different designating authorities in the Member States, regarding the assessment, designation, notification and re-assessment of CABs and NBs.

MDCG – Manual on borderline and classification under Regulations (EU) 2017/745 and 2017/746 September 2022

MDCG issued a Manual on borderline and classification of medical devices under the Regulations (EU) 2017/746 on medical devices ("MDR") and 2017/746 on in vitro diagnostic medical devices ("IVDR") in order to determine whether a given product falls under the definition of a medical device and whether the application of the classification rules falls within the competence of the authorities of the Member States where the product is on the market. Different interpretations of EU legislation may put public health at risk by distorting the internal market. Under those circumstances, this Manual lists the agreements reached by the Member State members of the Borderline and Classification Working Group ("BCWG") according to the MDR and IVDR.

The aspects concerning the borderline between medical devices and other types of products, also known as qualification of a product, are generally governed by Article 4 of the MDR and the corresponding Article 3 of the IVDR. Borderline cases are those for which it is not clear from the outset whether a given product is a medical device, or an in vitro diagnostic medical device ("IVD"), or not. Where a given product does not fall within the definition of medical device or is excluded from their scope, other EU or national legislation may be applicable. This Manual will however not provide indications to that effect.

Once a product is qualified as a medical device, a certain risk class will be assigned to it, namely I, IIa, IIb, and III. For a product qualified as an IVD, the risk classes are A, B, C and D. The aspects concerning classification of medical devices are governed by MDR Article 51 Classification of devices and Annex VIII Classification rules. For IVDR the corresponding references are Article 47 and Annex VIII.

Main purpose of this Manual is to standardize the classification process by guiding the competent authorities of the Member States towards the uniform application of the classification rules.

MDCG 2022-15 – Guidance on appropriate surveillance regarding the transitional provisions under Article 110 of the IVDR with regard to devices covered by certificates according to the IVDD September 2022

This guidance document outlines the activities to be performed by notified bodies as part of the appropriate surveillance defined in Article 110(3) last subparagraph of the IVDR. To clarify elements to be verified by notified bodies, this guidance document also covers requirements concerning certain manufacturers' obligations, especially in respect of their quality management system. The document applies to notified bodies that have lawfully issued certificates under Directive 98/79/EC on in vitro diagnostic medical devices ("IVDD"), regardless of whether or not those notified bodies have applied for designation or are designated under the IVDR (see MDCG 2019-10 rev. 18) as long as the respective authority responsible for notified bodies has the right to and does monitor the notified body's activities under Article 110(3) IVDR.

MedTech Europe – Making the EU Medical Devices Regulation more workable November 2022

MedTech Europe captured critical data in graphic form, calling for immediate and urgent action by EU institutions to improve the functionality of the MDR. According to the relevant press release, Europe is facing an imminent threat of shortages of medical devices needed by hospitals and physicians to care for patients, both in terms of new and existing devices. Despite the fact that the availability of medical devices is vital for patients, care teams and health systems across Europe, the implementation of the MDR seems to create massive product certification bottlenecks. Reportedly, MDR is a disincentive against launching innovation in the EU. As a result, new legally binding solutions and further clarity on existing measures are needed to ensure that the medical technology industry operates in a sustainable and efficient manner.

2023 EU4Health Work Programme November 2022

Within the EU4Health Work Programme 2023 adopted by the European Commission on November 21st 2022, there are several initiatives related to medical devices and in vitro diagnostic medical devices, and the implementation of the Regulations MDR and IVDR.

In particular the following ones:

- HS-g-23-62 Direct grant to EU reference laboratories for the Union contribution on in vitro diagnostic medical devices (p. 69-70)
- HS-p-23-63 Support to the technical secretariat for Notified Bodies Coordination Group (p. 106-107)
- HS-g-23-65 Call for proposals for a program on orphan medical devices, in particular targeting paediatric patients (p. 66-68)
- HS-p-23-67 Technical and administrative support to the medical device coordination group (MDCG) (p. 107)
- HS-p-23-68 Joint assessment of notified bodies (p. 107)
- HS-p-23-69 Support to EUDAMED (p. 108)

EOF's clarifications on clinical research and clinical performance studies November 2022

On November 21st, 2022, the National Organization for Medicines ("EOF") issued clarifications as regards medical devices clinical research and in vitro diagnostic medical devices clinical performance studies, providing guidance on internal procedures that depend on the type of studies. In particular:

As regards medical devices and Regulation (EU) 2017/745 ("MDR"):

(i) Clinical research falling under Article 62 of MDR, i.e. clinical investigations conducted to demonstrate conformity of medical devices, should be submitted to EOF for evaluation and approval;

(ii) Clinical research falling under Article 74(1) of MDR, i.e. clinical investigation to be conducted to further assess, within the scope of the intended purpose, a device which already bears the CE marking and where the investigation would involve submitting subjects to procedures additional to those performed under the normal conditions of use of the device and those additional procedures are invasive or burdensome, should be notified to EOF at least thirty (30) days before the start of the clinical research in Greece;

(iii) Clinical research subject to Article 82 of MDR, i.e. other clinical investigations, should not be submitted to EOF for approval.

As regards in vitro diagnostic medical devices and Regulation (EU) 2017/746 ("IVDR"):

(i) Clinical performance studies falling under Article 58 (paragraphs 1 and 2) of IVDR, i.e. any performance study in which a) surgically invasive sample-taking is done only for the purpose of the performance study; b) that is an interventional clinical performance study; or c) where the conduct of the study involves additional invasive procedures or other risks for the subjects of the studies; as well as performance studies involving companion diagnostics, should be submitted to EOF for evaluation and approval;

(ii) Clinical performance studies falling under Article 70(1) of IVDR, i.e. performance studies to be conducted to further assess, within the scope of the intended purpose, a device which already bears the CE marking and where the performance study would involve submitting subjects to procedures additional to those performed under the normal conditions of use of the device and those additional procedures are invasive or burdensome, should be notified to EOF at least thirty (30) days before the start of the performance studies in Greece;

(iii) Clinical performance studies falling under Article 58(2) of IVDR and specifically performance studies involving companion diagnostics where only left-over samples are used should be simply notified to EOF prior to the start of each study in Greece.

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