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INFORMATIVE NOTE

HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS

In-house devices used in health institutions established in the European Union

On 13 March 2023, INFARMED published the **Informative Circular 024/CD/100.20.200 of 10 March 2023**, which addresses the **European guidelines for devices manufactured and used in the respective health institution**.

Medical devices manufactured and used within EU health institutions on a non-industrial scale ("**in-house devices**") to address specific needs of target patient groups which cannot be met or cannot be met at the appropriate level of performance by an equivalent device available on the market **are exempt from most of the provisions** of (i) **Regulation (EU) 2017/745** of the European Parliament and of the Council of 5 April 2017 on **medical devices** ("**MDR**") and (ii) **Regulation (EU) 2017/746** of the European Parliament and of the Council of 5 April 2017 on **in vitro diagnostic medical devices** ("**IVDR**"), provided they comply with the applicable general safety and performance requirements.

For this exemption to apply, the health institution must meet the conditions set out in Article 5(5) of the applicable regulation, the MDR or the IVDR.

The regulations define a "health institution" as an **organisation** whose primary purpose is to **provide care or treatment to patients or to promote public health**. This includes both **hospitals** and **public health institutions**, **laboratories** and **institutes** that support the health system and/or respond to the needs of patients, even if they do not directly treat or care for patients. Establishments that claim to promote health or healthy lifestyles, such as gyms, spas, wellness and fitness centres, are explicitly excluded. In addition, this only applies to **healthcare institutions in the European Union**.

Medical devices manufactured and used within EU health institutions on a non-industrial scale, are exempt from most of the provisions of Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices.

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In order to ensure a harmonised application of this exemption, in January, the Medical Device Coordination Group published a document which provides guidance on the implementation of some of the requirements of Article 5(5).

The Regulation also provides that any natural or legal person providing diagnostic or therapeutic services by **distance selling** to patients in the European Union must comply with the provisions of the applicable regulation.

In order to ensure a harmonised application of this exemption, in January 2023, the Medical Device Coordination Group ("MDCG") published the document **"MDGC 2023-1: Guidance on the health institution exemption under Article 5(5) of Regulation EU 2017/745 and Regulation (EU) 2017/746"**. This document provides guidance on the implementation of some of the requirements of Article 5(5) and is intended for health professionals and researchers in health institutions who wish to design, manufacture, modify and use in-house devices.

In any case, Member States retain the right to restrict the manufacture and use of certain types of these devices and to monitor the activities of healthcare institutions.

In the case of the MDR, Article 5(5), which provides for this exemption, will be fully applicable from May 2021.

In the case of the IVDR, the application is postponed by subparagraphs - the article will not be fully applicable until May 2028. ■