MDR for Point-of-Care 3D printing facilities:

8 rules

As of May 26, 2021, the new Medical Device Regulation will be fully applicable. This infographic summarizes article 5.5 of the MDR, explaining which rules Point-of-Care 3D Printing facilities must follow to manufacture medical devices without meeting all requirements typically required of a medical device manufacturer.

01

All (3D-printed) medical devices must be printed and used within the **same legal entity**.

02

All Point-of-Care 3D printing facilities must manufacture and use devices under an **appropriate quality management system (QMS)** – a system that aims to document and facilitate the implementation of important processes, reduce mistakes, and ensure quality and safety.

03

Hospitals must **justify** why devices are **3D printed in-house rather than purchased** based on patients' specific needs. Examples of such justification could include lead time, accessibility, or flexibility on the device's design.

04

All information needs to be available to competent authorities **upon request**.

05

Publicly declare:

- The **name** and **address** of the manufacturing health institution
- The details necessary to **identify the devices**
- That the devices meet the general safety and performance requirements set out in Annex 1 to the Regulation, and, if necessary, explain which are not fully satisfied and why.

06

Create **documentation** that clearly explains:

- That the **general safety and performance** requirements are met
- The **manufacturing facility** and **process**
- The **design, intended purpose**, and **performance data** of the devices.

07

3D printing facilities must **ensure** and **prove** that 3D-printed devices are manufactured in accordance with the documentation referred to in **point 6**.

08

Review post-manufacturing data gained from clinical use of the devices, including the clinical outcomes, and take all necessary corrective actions. A **periodical review** process must also exist.

Member States may require that health institutions submit any further relevant information about devices that have been manufactured and used on their territory to the competent authority. They also have the right to restrict the manufacture and use of any specific type of such devices and must be permitted access to inspect the health institutions' activities.

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