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MDCG 2020-3 Rev.1: Updates to MDR Significant Changes

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On 12 May 2023, the Medical Device Coordination Group ("MDCG") issued a revised version of its guidance document on significant changes under Article 120 par. 3(c) point (b) of the Regulation (EU) 2017/745 on medical devices ("MDR") (the "Guidance"), which contained adjustments aiming at its alignment with Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices as well as MDCG 2022-2 Guidance on general principles of clinical evidence for in vitro diagnostic medical devices (IVDs). The Guidance also "takes into account the experience gained with the application of the original version so far".

Pursuant to the Guidance "legacy devices", meaning devices which:

- are covered by a valid certificate issued in accordance with the Directive 93/42/EEC concerning medical devices ("MDD") or Directive 90/385/EEC relating to active implantable medical devices ("AIMDD") prior to the date of entry into application of the MDR; or

- are Class I devices under the MDD, for which an EC declaration of conformity has been drawn up prior to the date of entry into application of the MDR and for which the conformity assessment procedure under the MDR requires the involvement of a notified body;

may continue to be placed on the market or put into service until 31 December 2027 or 31 December 2028 (depending on their classification) provided that they continue to comply with the provisions of the MDD or the AIMDD and that there are no significant changes in their design or intended purpose.

The purpose of the Guidance is to provide clarifications regarding which changes are considered "significant" and would, thus, trigger the requirement for legacy devices to obtain certification under the MDR, by presenting relevant examples.

Therefore, as per the Guidance, a significant change according to Article 120 par. 3 (c), point (b) of the MDR consists of the following cumulative elements:

- It refers to the design or intended purpose of the device; and
- Said change is significant.

According to the Guidance, in case of doubt regarding whether a certain change, which concerns the intended purpose, or the design of the medical device covered by a certificate issued by a notified body, is significant or not, manufacturers as advised to consult a notified body, which shall be notified of and verify any change to the device either as part of its surveillance activities, or following a manufacturer's submission of the change for prior approval. When the notified body, after

having reviewed the description of the (proposed) change, considers that said change does not constitute a "significant change" under Article 120 par. 3 (c) point (b) of the MDR, it may provide a written confirmation to that effect. Such written confirmation shall correct or complement information on the existing certificate of the legacy device.

The Guidance contains relevant examples of changes that are not considered as changes in the design or intended purpose of a medical device. These are - among others - the following:

- Changes to the manufacturer's name, address or legal form, including a merger or acquisition involving the manufacturer;
- Changes in relation to the authorized representative;

It further provides examples of changes in the design and/or intended purpose, which however, are not considered as significant. These are *inter alia* the following:

- Updates of the information to be supplied with the device (e.g. label, instructions for use or implant card) if they are required by EU legislation other than the MDR;
- Limitations or extensions of the intended purpose;
- Changes that do not alter the device's built-in control mechanism;
- Changes in the outer packaging (e.g. size, material, layout), which do not adversely affect the stability, sterility or microbiological state of the device.

As regards the changes that are considered significant, the Guidance provides -among others- the following examples:

- Change in the design that alters the built-in control mechanism of the device;
- Change from manual to software-driven device;
- Change to measuring function wavelength or light emission;
- New user interface, such as:
  - Change from keyboard input to touchscreen;
  - Change from keyboard to wireless remote control;
  - Software changes that impact the way data is read or interpreted by the user;
- New medical feature or functionality that may change the diagnosis or the therapy delivered to the patient;

Finally, the Guidance includes decision tree flow charts, which facilitate the assessment of whether an intended purpose or design change is considered significant.

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