
29th September 2023

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CVR-nr.69749917

To whom it may concern.

Declaration of Manufacturer Stating the Fulfilment of Extension Conditions

The undersigned, acting as Vice President of Global Regulatory Affairs at Coloplast, hereby confirms that Coloplast A/S, located Holtedam 1, 3050 Humlebaek, Denmark, has obtained an extension of the validity of its conformity assessment certificates issued by the Notified Body DNV (NB #2460) issued under the Medical Devices Directive 93/42/CEE (MDD), in accordance with the provisions set by the Regulation EU 2023/607 amending Regulations (EU) 2017/745 (MDR).

The medical devices in scope of this extension are those listed in the Notified Body Confirmation Letter #C627818 issued by DNV and dated 20 September 2023.

Consistent with the provisions set out in Article 120 of the MDR, as amended, this extension entails the following conditions:

- those devices continue to comply with the MDD;
- there are no significant changes in the design and intended purpose;
- the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;
- Coloplast A/S has put in place a quality management system in accordance with applicable provisions of the MDR;
- Coloplast A/S has lodged a formal application and has signed a mutual agreement with the Notified Body DNV for continued surveillance under MDD and conformity assessment under the MDR, as applicable.

Attachments

- Confirmation Letter #C627818, 12 pages.



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