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Declaration of biocompatibility conformity

To LINAK customers,

LINAK hereby declares that the LINAK MEDLINE® & CARELINE® products, which are incorporated into electrical medical equipment and systems, comply with IEC 60601-1:2020 clause 11.7.

All parts of these products that may come into contact with the skin surface of a patient or user during normal use have been assessed for biocompatibility as part of the ISO 14971:2019 risk management process.

This assessment is based on post-market experience with similar devices and materials, as well as the anticipated nature and duration of contact with human tissues during use.

The frequency and cumulative duration of exposure, along with the identified hazards, make no further biological evaluation necessary, in accordance with ISO 10993-1:2025 clause 4.1. Accessible parts of the products are made from materials commonly used in other medical devices with a similar nature of contact. LINAK maintains construction records for a minimum of 10 years after the product has been withdrawn from the market. The assessment is based on LINAK products being non-invasive and intended for contact with intact skin only.

It is the responsibility of the manufacturer of the medical equipment or system, which has completed all manufacturing processes for the medical device to be marketed, including packaging and, if applicable, sterilisation, to assess biological risk.

Best regards
LINAK A/S

Jette Jensen
Vice President, Quality