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LINAK A/S
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# DECLARATION OF BIOCOMPATIBILITY CONFORMITY

To LINAK customers

Hereby declares, that LINAK MEDLINE® & CARELINE® products, intended to be incorporated into electrical medical equipment and systems, comply with IEC 60601-1:2020 clause 11.7.
All parts of the products, that in normal use can come into contact with the skin surface of the patient or the user, are assessed with respect to biocompatibility within the scope of the ISO 14971:2019 risk management process activities.
Assessment is according to postmarked experience from similar devices and materials and the nature and duration of their anticipated contact with human tissues when in use.
The frequency and cumulative duration of the exposure and the hazards identified makes no further biological evaluation needed, according to ISO 10993-1:2018 clause 5.2.2 a).
Accessible parts of the products can be shown to be made from materials in common use for other medical and consumer products with a similar nature of contact, LINAK maintains a construction record for at the least 10 years after the product has been withdrawn from the market.

The assessment is based on LINAK products being non-invasive and in touch with intact skin only.
It is the responsibility of the manufacturer of the medical equipment or system, that has been subjected to all manufacturing processes for the “to be marketed” medical device including packaging and if applicable, sterilization, to assess biological risk

Best regards
Jette Jensen
Vice President, Quality
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