

DECLARATION OF CONFORMITY

(Manufacturer's Declaration)

Manufacturer: SBO Hearing A/S
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Single Registration Number (SRN): DK-MF-000001270

This declaration of conformity is issued under the sole responsibility of SBO Hearing A/S.

Product Names: Oticon Remote Control 3.0
Remote Control 3.0

Model Name: RC-3A

Basic UDI-DI: 57144640-RC-00025-UN

The Manufacturer hereby declares that the listed accessory to hearing aids are in conformity with the essential requirements and other relevant requirements of the following Directives and Regulations:

EU Medical Device Regulation (MDR) 2017/745

To fulfill the European requirements concerning medical devices, the manufacturer has established a full quality assurance system described in Article 52, req. 7 of the MDR for class I devices. The Manufacturer's quality management system is compliant with DS/EN ISO 13485 certified by TÜV SÜD Product Service GmbH on ISO certificate Q5 003348 0002.

The following Common Specification(s) are used to declare this conformity: N/A

EU Radio Equipment Directive (RED) 2014/53/EU

Conformity assessment to Article 3 – Essential Requirements performed by SBO Hearing A/S

EU RoHS Directive 2011/65/EU and amendment Commission Delegated Directive (EU) 2015/863 amending Annex II to Directive 2011/65/EU

Conformity assessment to restriction of the use of certain hazardous substances in electrical and electronic equipment directive including all applicable amendments performed by SBO Hearing A/S.

Signed in Smørum 2021-05-19 on behalf of SBO Hearing A/S


Mette Bang Dyrberg
Senior Director, Regulatory Affairs



SBO Hearing A/S