

# 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 ConnectClip  
ConnectClip  
**Model Name:** AC1A  
**Basic UDI-DI:** 57144640-AC-00034-GH

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:

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## **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

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

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

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## **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.

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

  
Mette Bang Dyhrberg  
Senior Director, Regulatory Affairs



**SBO Hearing A/S**