DECLARATION OF CONFORMITY

(Manufacturer's Declaration)

Manufacturer: SBO Hearing A/S
Kongebakken 9
DK-2765 Smørum
Denmark
Telephone +45 39 17 71 00
Fax +45 39 27 79 00
Single Registration Number (SRN): DK-MF-000001270

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

The Manufacturer hereby declares that the listed medical devices 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 fulfil the European requirements concerning medical devices, the manufacturer has established a full quality assurance system as described in Annex IX of the MDR for class IIa devices (excluding not applicable sections) supported by EU certificate G10 003348 0004 (with related product list) issued by the Manufacturer's Notified Body (NB) 0123 TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 Munich, Germany

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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.

EU RoHS Directive 2011/65/EU and amendment Commission Delegated Directive (EU) 2015/863 amending Annex II to Directive 2011/65/EU and applied standard IEC 63000:2016 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 2023-05-04 on behalf of SBO Hearing A/S

Mette Bang Dyhrberg
Senior Director, Regulatory Affairs
Person Responsible for Regulatory Compliance

CE 0123

SBO Hearing A/S

Medical devices covered by this declaration of conformity:

Product identification *(Medical Device Description)*	**Brand**	**Basic UDI-DI**
Bernafon LX7 BTE SP	Bernafon	57144640-HI-000015-WT
Bernafon LX3 BTE SP		
Bernafon LX7 BTE UP		
Bernafon LX3 BTE UP		