

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:

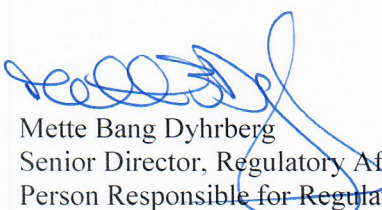
EU Medical Device Regulation (MDR) 2017/745

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 EC 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

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 2022-02-10 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 <i>(Medical Device Description)</i>	Brand	Basic UDI-DI		
Bernaфон Alpha 9 MNB T	Bernaфон	57144640-HI-00053-RB		
Bernaфон Alpha 9 MNB T R				
Bernaфон Alpha 7 MNB T				
Bernaфон Alpha 7 MNB T R				
Bernaфон Alpha 5 MNB T				
Bernaфон Alpha 5 MNB T R				
Bernaфон Alpha 3 MNB T				
Bernaфон Alpha 3 MNB T R				
Bernaфон Alpha 3 MNR T				
Bernaфон Alpha 3 MNR T R				
Bernaфон Alpha 1 MNB T				
Bernaфон Alpha 1 MNB T R				
Bernaфон Alpha 1 MNR T				
Bernaфон Alpha 1 MNR T R				
AO9 MNB T			Neutral (GPL)	57144640-HI-00053-RB
AO9 MNB T R				
AO7 MNB T				
AO7 MNB T R				
AO5 MNB T				
AO5 MNB T R				
AO3 MNB T				
AO3 MNB T R				
AO3 MNR T				
AO3 MNR T R				
AO1 MNB T				
AO1 MNB T R				
AO1 MNR T				
AO1 MNR T R				
Pro Akustik pro+4 AO9 MNB T	Pro Akustik	57144640-HI-00053-RB		
Pro Akustik pro+4 AO9 MNB T R				
Pro Akustik pro+4 AO7 MNB T				
Pro Akustik pro+4 AO7 MNB T R				
Pro Akustik pro+4 AO5 MNB T				
Pro Akustik pro+4 AO5 MNB T R				
Pro Akustik pro+4 AO3 MNB T				
Pro Akustik pro+4 AO3 MNB T R				
Pro Akustik pro+4 AO3 MNR T				
Pro Akustik pro+4 AO3 MNR T R				
Pro Akustik pro+4 AO1 MNB T				
Pro Akustik pro+4 AO1 MNB T R				
Pro Akustik pro+4 AO1 MNR T				
Pro Akustik pro+4 AO1 MNR T R				

Maico AO9 MNB T	Maico	57144640-HI-00053-RB
Maico AO9 MNB T R		
Maico AO7 MNB T		
Maico AO7 MNB T R		
Maico AO5 MNB T		
Maico AO5 MNB T R		
Maico AO3 MNB T		
Maico AO3 MNB T R		
Maico AO3 MNR T		
Maico AO3 MNR T R		
Maico AO1 MNB T		
Maico AO1 MNB T R		
Maico AO1 MNR T		
Maico AO1 MNR T R		
SoniTon AO9 MNB T	SoniTon	57144640-HI-00053-RB
SoniTon AO9 MNB T R		
SoniTon AO7 MNB T		
SoniTon AO7 MNB T R		
SoniTon AO5 MNB T		
SoniTon AO5 MNB T R		
SoniTon AO3 MNB T		
SoniTon AO3 MNB T R		
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SoniTon AO3 MNR T R		
SoniTon AO1 MNB T		
SoniTon AO1 MNB T R		
SoniTon AO1 MNR T		
SoniTon AO1 MNR T R		
Audilab AO9 MNB T	Audilab	57144640-HI-00053-RB
Audilab AO9 MNB T R		
Audilab AO7 MNB T		
Audilab AO7 MNB T R		
Audilab AO5 MNB T		
Audilab AO5 MNB T R		
Audilab AO3 MNB T		
Audilab AO3 MNB T R		
Audilab AO3 MNR T		
Audilab AO3 MNR T R		
Audilab AO1 MNB T		
Audilab AO1 MNB T R		
Audilab AO1 MNR T		
Audilab AO1 MNR T R		
MicroAudio AO9 MNB T	MicroAudio	57144640-HI-00053-RB
MicroAudio AO9 MNB T R		
MicroAudio AO7 MNB T		

MicroAudio AO7 MNB T R		
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Bernafon AO1 MNR T		
Bernafon AO1 MNR T R		