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 following Common Specification(s) are used to declare this conformity: NA

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 0005 (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 2022-09-15 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)*	**KIT identification**	**Brand**	**Basic UDI-DI**
Sonic Radiant 100 IIC	Radiant 100 KIT IIC 10 75 Radiant 100 KIT IIC 10 90	Sonic	57144640-HI-00078-S4
Sonic Radiant 100 CIC	Radiant 100, KIT 10 75 Radiant 100, KIT 10 75 PB Radiant 100, KIT 10 90 Radiant 100, KIT 10 90 PB Radiant 100, KIT 10 NFM 75 Radiant 100, KIT 10 NFM 75 PB Radiant 100, KIT 10 NFM 90 Radiant 100, KIT 10 NFM 90 PB		
Sonic Radiant 100 ITC	Radiant 100, KIT 312 2.4G NFM 90 Radiant 100, KIT 312 2.4G NFM 90 PB Radiant 100, KIT 312 2.4G NFM Radiant 100, KIT 312 2.4G NFM PB Radiant 100, KIT 312 NFM 90 Radiant 100, KIT 312 NFM 90 PB Radiant 100, KIT 312 NFM Radiant 100, KIT 312 NFM PB		
Sonic Radiant 100 ITE HS Sonic Radiant 100 ITE FS	Radiant 100, KIT 312 2.4G NFM 90 Radiant 100, KIT 312 2.4G NFM 90 PB Radiant 100, KIT 312 2.4G NFM Radiant 100, KIT 312 2.4G NFM PB Radiant 100, KIT 312 NFM 90 Radiant 100, KIT 312 NFM 90 PB Radiant 100, KIT 312 NFM Radiant 100, KIT 312 NFM PB		
Sonic Radiant 80 IIC	Radiant 80 KIT IIC 10 75 Radiant 80 KIT IIC 10 90		
Sonic Radiant 80 CIC	Radiant 80, KIT 10 75 Radiant 80, KIT 10 75 PB Radiant 80, KIT 10 90 Radiant 80, KIT 10 90 PB Radiant 80, KIT 10 NFM 75 Radiant 80, KIT 10 NFM 75 PB Radiant 80, KIT 10 NFM 90 Radiant 80, KIT 10 NFM 90 PB		
Sonic Radiant 80 ITC	Radiant 80, KIT 312 2.4G NFM 90 Radiant 80, KIT 312 2.4G NFM 90 PB Radiant 80, KIT 312 2.4G NFM Radiant 80, KIT 312 2.4G NFM PB Radiant 80, KIT 312 NFM 90 Radiant 80, KIT 312 NFM 90 PB Radiant 80, KIT 312 NFM Radiant 80, KIT 312 NFM PB		
Sonic Radiant 80 ITE HS Sonic Radiant 80 ITE FS	Radiant 80, KIT 312 2.4G NFM 90 Radiant 80, KIT 312 2.4G NFM 90 PB Radiant 80, KIT 312 2.4G NFM Radiant 80, KIT 312 2.4G NFM PB Radiant 80, KIT 312 NFM 90 Radiant 80, KIT 312 NFM 90 PB Radiant 80, KIT 312 NFM Radiant 80, KIT 312 NFM PB		
Sonic Radiant 60 IIC	Radiant 60 KIT IIC 10 75 Radiant 60 KIT IIC 10 90		

Sonic Radiant 60 CIC	Radiant 60, KIT 10 75 Radiant 60, KIT 10 75 PB Radiant 60, KIT 10 90 Radiant 60, KIT 10 90 PB Radiant 60, KIT 10 NFM 75 Radiant 60, KIT 10 NFM 75 PB Radiant 60, KIT 10 NFM 90 Radiant 60, KIT 10 NFM 90 PB		
Sonic Radiant 60 ITC	Radiant 60, KIT 312 2.4G NFM 90 Radiant 60, KIT 312 2.4G NFM 90 PB Radiant 60, KIT 312 2.4G NFM Radiant 60, KIT 312 2.4G NFM PB Radiant 60, KIT 312 NFM 90 Radiant 60, KIT 312 NFM 90 PB Radiant 60, KIT 312 NFM Radiant 60, KIT 312 NFM PB		
Sonic Radiant 60 ITE HS Sonic Radiant 60 ITE FS	Radiant 60, KIT 312 2.4G NFM 90 Radiant 60, KIT 312 2.4G NFM 90 PB Radiant 60, KIT 312 2.4G NFM Radiant 60, KIT 312 2.4G NFM PB Radiant 60, KIT 312 NFM 90 Radiant 60, KIT 312 NFM 90 PB Radiant 60, KIT 312 NFM Radiant 60, KIT 312 NFM PB		
Sonic Radiant 40 IIC	Radiant 40 KIT IIC 10 75 Radiant 40 KIT IIC 10 90		
Sonic Radiant 40 CIC	Radiant 40, KIT 10 75 Radiant 40, KIT 10 75 PB Radiant 40, KIT 10 90 Radiant 40, KIT 10 90 PB Radiant 40, KIT 10 NFM 75 Radiant 40, KIT 10 NFM 75 PB Radiant 40, KIT 10 NFM 90 Radiant 40, KIT 10 NFM 90 PB		
Sonic Radiant 40 ITC	Radiant 40, KIT 312 2.4G NFM 90 Radiant 40, KIT 312 2.4G NFM 90 PB Radiant 40, KIT 312 2.4G NFM Radiant 40, KIT 312 2.4G NFM PB Radiant 40, KIT 312 NFM 90 Radiant 40, KIT 312 NFM 90 PB Radiant 40, KIT 312 NFM Radiant 40, KIT 312 NFM PB		
Sonic Radiant 40 ITE HS Sonic Radiant 40 ITE FS	Radiant 40, KIT 312 2.4G NFM 90 Radiant 40, KIT 312 2.4G NFM 90 PB Radiant 40, KIT 312 2.4G NFM Radiant 40, KIT 312 2.4G NFM PB Radiant 40, KIT 312 NFM 90 Radiant 40, KIT 312 NFM 90 PB Radiant 40, KIT 312 NFM Radiant 40, KIT 312 NFM PB		
Sonic Radiant 20 IIC	Radiant 20 KIT IIC 10 75 Radiant 20 KIT IIC 10 90		
Sonic Radiant 20 CIC	Radiant 20, KIT 10 75 Radiant 20, KIT 10 75 PB Radiant 20, KIT 10 90 Radiant 20, KIT 10 90 PB Radiant 20, KIT 10 NFM 75 Radiant 20, KIT 10 NFM 75 PB		

	Radiant 20, KIT 10 NFM 90 Radiant 20, KIT 10 NFM 90 PB		
Sonic Radiant 20 ITC	Radiant 20, KIT 312 2.4G NFM 90 Radiant 20, KIT 312 2.4G NFM 90 PB Radiant 20, KIT 312 2.4G NFM Radiant 20, KIT 312 2.4G NFM PB Radiant 20, KIT 312 NFM 90 Radiant 20, KIT 312 NFM 90 PB Radiant 20, KIT 312 NFM Radiant 20, KIT 312 NFM PB		
Sonic Radiant 20 ITE HS Sonic Radiant 20 ITE FS	Radiant 20, KIT 312 2.4G NFM 90 Radiant 20, KIT 312 2.4G NFM 90 PB Radiant 20, KIT 312 2.4G NFM Radiant 20, KIT 312 2.4G NFM PB Radiant 20, KIT 312 NFM 90 Radiant 20, KIT 312 NFM 90 PB Radiant 20, KIT 312 NFM Radiant 20, KIT 312 NFM PB		