WIDEX

EU DECLARATION OF CONFORMITY

Manufacturer	**WSAUD A/S** Nymoellevej 6 DK-3540 Lynge Denmark
Brand:	**WIDEX**
Product Family:	MAGNIFY
Type of Device:	Hearing Aids
Basic UDI-DI:	5714880-WSA-72-10-47 (BTE) 5714880-WSA-72-15-4N (RIC) 5714880-WSA-72-25-4T (Custom)
Single registration number:	DK-MF-000015974
GMDN Code:	34671 Behind-the-ear air conduction hearing aid 47169 Receiver-in-canal air-conduction hearing aid 34672 In-the-ear airconduction hearing aid
EMDN Code:	Y2145060101 BEHIND-THE-EAR HEARING AIDS WITH RECEIVER IN THE DEVICE (BTE) Y2145060102 BEHIND-THE-EAR HEARING AIDS WITH RECEIVER IN THE CANAL (RIC, RITE) Y21450602 IN-THE-EAR HEARING AIDS (ITEs)
Product Identification:	See next page

We declare under our sole responsibility that above products are in conformity with the following Regulations and Directives:

REGULATION (EU) 2017/745 (MDR) OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

Conformity assessment procedure:	Annex IX of Regulation (EU) 2017/745
Notified Body:	TÜV SÜD Product Service GmbH, Notified Body No.: NB 0123 Ridlerstr. 65, 80339 München, Germany
Classification of device:	**Class IIa** (according to Annex VIII Rule 9 to Regulation (EU) 2017/745)

The products meet all applicable standards and the general safety and performance requirements of the Regulation (EU) 2017/745 Annex I. Applicable standards are listed in the respective technical documentation.

Council Directive 2011/65/EU (RoHS) as amended by Dir. 2017/2102/EC (RoHS2)

Relevant Harmonized Standards: EN62321

Council Directive 2014/53/EU (RED)

Relevant Harmonized Standards:

Standard versions valid on the date when this DoC is issued.

EN 62479, EN 301 489-1, EN 301 489-3, EN 301 489-17, EN 300 330, EN 300 328, EN 300 422-4

WIDEX

EU DECLARATION OF CONFORMITY

Product Identification	Type of Device
MBB3D (-, M44, M33, M22, M11, M10, M05, M06, DEMO M10, DEMO M06, DEMO M05)	**BTE (Behind The Ear) Hearing Aid** including earmoulds
MBB3 (M04, M03)	
MBR3D (-,M44, M33, M22, M11, M10, DEMO M10)	
MBB2 (RC, M04, M06, DEMO M06)	
MRB0 (RIC 10, M04, M06, DEMO M06) MRB2D (T-RIC 312 D, M06, DEMO M06)	**RIC (Receiver In the Canal) Hearing Aid**
M-XP (T, M04, M06)	**ITE (In The Ear) Hearing Aid including faceplate***
M-CIC (L, R, M04, M06) M-CIC TR (L, R, M04, M06) M-CIC-M (M04, M06) M-CIC-M TR (M04, M06)	**Canal air-conduction hearing aid**

This Declaration of Conformity includes all hearing aid components and spare parts of the products listed above.

Place and valid from date: Lynge, March 17, 2022

Name: Malene Giese Jakobsen
Sr. Regulatory Affairs Specialist

Signature: Malene Giese Jakobsen

This declaration will be renewed on any significant change of product, product range, standards and laws.

*A Custom made Faceplate is an integral component of the final Product(s) mentioned on this declaration of conformity. Pres-assemblies or configurable variants where CFPS can be made off, are part of the Design Review release process of the Product.