

EU DECLARATION OF CONFORMITY

Manufacturer	WSAUD A/S Nymoellevej 6 DK-3540 Lyngø Denmark
Brand:	WIDEX
Product Family:	MOMENT
Type of Device:	Hearing Aids
Basic UDI-DI:	5714880-WSA-65-10-4T (BTE) 5714880-WSA-65-15-5A (RIC, RITE) 5714880-WSA-65-17-5G (RIC, RITE) 5714880-WSA-65-58-67 (Charger)
Single registration number:	DK-MF-000015974
GMDN Code:	34671 Behind-the-ear airconduction hearing aid 47169 Air-conduction hearing aid, receiver-in-canal 17115 Non-invasive device battery charger
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) Y214580 HEARING AIDS OR HEARING DEVICES - ACCESORIES
Product Identification:	See next page(s)

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
EC certificate (valid at ver. 1 of this Declaration of Conformity):	EC certificate number: No. G10 105767 0002 Rev. 00
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: EN IEC 63000

Council Directive 2014/53/EU (RED)

Relevant Harmonized Standards: EN 300 330, EN 300 328, EN 300 422-4

Standard versions as listed in the respective technical documentation

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Other Relevant Standards

EN 62479, EN 301 489-3, EN 301 489-1, EN 301 489-17

Product Identification	Type of Device
MBB3D (-, 440, 330, 220, 110, DEMO 440)	BTE (Behind The Ear) Hearing Aid including earmoulds
MBR3D (-, 440, 330, 220, 110, DEMO 440)	
MRR4D (-, 440, 330, 220, 110, DEMO)	RIC (Receiver In the Canal) Hearing Aid
MRRLD (-, 440, 330, 220, 110, DEMO)	
KIT MRRLD (-, 440, 330, 220, 110, DEMO)	RIC (Receiver In the Canal) Hearing Aid & Charger for hearing aids

This Declaration of Conformity includes all hearing aid components and spare parts like earmold, or hooks of the products listed above.

Place and valid from date

Lynge, January 16, 2024

Name

Malene Giese Jakobsen

Sr. Regulatory Affairs Specialist

Signature

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