

EC DECLARATION OF CONFORMITY

Manufacturer WIDEX A/S

Nymøllevej 6 DK-3540 Lynge

Denmark

Brand: WIDEX

Product Family: MAGNIFY

Type of Device: Hearing Aids

GMDN Code: 34671 Behind-the-ear air conduction hearing aid

47169 Receiver-in-canal air-conduction hearing aid

34672 In-the-ear air-conduction hearing aid 41209 Canal air-conduction hearing aid

Product Identification: See next page<s>

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

Council Directive 93/42/EEC as amended by Dir. 2007/47/EC (MDD)

Conformity assessment Annex II without chapter II.4 of 93/42/EEC

procedure:

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 IX to Council Directive 93/42/EEC)

The products meet the applicable standards and the basic requirements of the Directive 93/42/EEC

Annex I.

Applicable standards are listed in the respective technical file.

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

Relevant Harmonized Standards: EN 62321

Council Directive 2014/53/EU (RED)

Applied standards:

(with Bluetooth interface)

EN 300 328, EN 301 489-1, EN 301 489-17

Applied Standards

(with Telecoil)

EN 300 422-4

Applied Standards EN 300 330, EN 301 489-1, EN 301 489-3

(with wireless function)

The products are in compliance with the essential requirement of the directive.

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Place and valid from date Lynge, August 11, 2021

Name Malene Giese Jakobsen

Sr. Regulatory Affairs Specialist

Signature Kolen Gier Ockobs

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



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Product Identification	Type of Device
MBB2 (RC, -, M03, M05, M10, M11,M22,M33,M44, DEMO100, DEMO50)	BTE (Behind The Ear) Hearing Aid
MRR2D (RC-mRIC R D, -, M10, M11, M22, M33, M44, DEMO100)	RIC (Receiver In the Canal) Hearing Aid
MRB0 (RIC 10, -, M03, M05, M10, M11,M22,M33,M44, DEMO100)	
MRB2D (T-RIC 312 D, -, M05, M10, M11, M22, M33, M44, DEMO100, DEMO50)	
M-XP (T, -, M03, M05, M10, M11, M22, M33, M44)	ITE (In The Ear) Hearing Aid including faceplate*
M-IM (L, R, -, M11,M22,M33,M44)	
M-IP (L, R, -, M11,M22,M33,M44)	
M-CIC (L, R, -, M03, M05, M10, M11,M22,M33,M44)	Canal air-conduction hearing aid
M-CIC TR (L, R, -, M03, M05, M10, M11, M22, M33, M44)	
M-CIC-M (-,M03, M05, M10, M11,M22,M33,M44)	
M-CIC-M TR (-,M03, M05, M10, M11,M22,M33,M44)	

^{*}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.