

EC DECLARATION OF CONFORMITY

Manufacturer

Widex A/S

Nymøllevej 6 DK-3540 Lynge

Denmark

Brand:

WIDEX

Product Family:

MOMENT

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 (with wireless function) EN 300 330, EN 301 489-1, EN 301 489-3

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

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Place and valid from date Lynge, May 07, 2021

Name Malene Giese Jakobsen

Sr. Regulatory Affairs Specialist

Signature <u>Maleri Giese Dichelsen</u>

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, -, 110,220,330,440, 440 DEMO)	BTE (Behind The Ear) Hearing Aid
MRR2D (RC-mRIC R D, -, 110,220,330,440, 440 DEMO) MRB0 (RIC 10, -, 110,220,330,440,	RIC (Receiver In the Canal) Hearing Aid RITE (Receiver in the Ear) Hearing Aid
440 DEMO) MRB2D (T-RIC 312 D, -, 110,220,330,440, 440 DEMO)	
M-XP (T, -, 110,220,330,440) M-IM (L, R, -, 110,220,330,440) M-IP (L, R, -, 110,220,330,440)	ITE (In The Ear) Hearing Aid including faceplate*
M-CIC (L, R, -, 110,220,330,440) M-CIC TR (L, R, -, 110,220,330,440) M-CIC-M (-, 110,220,330,440) M-CIC-M TR (-, 110,220,330,440)	Canal air-conduction hearing aid

^{*}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.