

EU DECLARATION OF CONFORMITY

Manufacturer

Widex A/S

Nymoellevej 6 DK-3540 Lynge

Denmark

Brand:

WIDEX

Product Family:

WIDEX ACESSORIES

Type of Device:

Remote Control for Hearing Aids

Basic UDI-DI:

5706069-WDX-63-60-66

Single registration number:

N/A

GMDN Code:

57885 Hearing aid remote control

Product Identification:

See below

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

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

Conformity assessment procedure:

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

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:

EN62321

Council Directive 2014/53/EU (RED)

Relevant Harmonized Standards:

EN 62479, EN 301 489-1, EN 301 489-3, EN 300 330

Standard versions valid on the date

when this DoC is issued.

Product Identification	Type of Device
RC-DEX	Remote control for hearing aid

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



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Place and valid from date	Lynge, November 02, 2021
Name	Hans-Otto Bindeballe
	Global Regulatory Affairs Manager

Signature

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