

EC Declaration of Conformity

We, manufacturer **Widex A/S**
Nymoellevej 6
DK-3540 Lynge
Denmark

Declare under our sole responsibility that the following **PRODUCTS** starting with Serial no. 10.000

Brand: Widex
 Series: DAILY
 Description: Hearing Aid

Model	Variant(s)	Type	GMDN code	GMDN Term
D-9	T-RC, T-VC-RC	BTE	34671	Behind-the-ear air-conduction hearing aid
D-FA	T-VC-RC			
D-FA P	T-VC-RC			
D-m CB	RC			
D-PA	RC	RIC	47169	Receiver-in-canal air-conduction hearing aid
D-FS	T-RC	RIC, RITE		
D-XP	T-RC	ITE	34672	In-the-ear air-conduction hearing aid
D-CIC	RC-R, RC-L	CIC	41209	Canal air-conduction hearing aid
D-CIC-TR	RC-R, RC-L			
D-CIC-M	NA			
D-CIC-M-TR	NA			

are in conformity with the essential requirements and other applicable provisions of the following **EU Directives**:

Council Directive 93/42/EEC as amended by Dir. 2007/47/EC (MDD)
Directive 1999/5/EC (R&TTE)
Directive 2011/65/EU (RoHS 2)

Conformity assessment procedure	MDD : Annex II of 93/42/EEC R&TTE : Annex III of 1999/5/EC
Notified Body	MDD : LNE/G-MED, Notified Body No.: NB 0459
EC-Certificate	MDD : No. 7471
Classification of Device	MDD : Class IIa, Rule 9 according to 93/42/EEC Annex IX
Applied standards and specifications in conformity assessment. Standard versions valid on the date when this DoC is issued.	MDD : EN 1041, EN 10993-1, EN 13485, EN 14155, EN 14971, ISO 15223-1, EN 50419, EN 60118-0, EN 60118-6, EN 60118-7, EN 60118-13, EN 60601-1-2, EN 62366 R&TTE : EN 60950-1, EN 62479, EN 301 489-1, EN 301 489-3, EN 300 330-2 RoHS 2 : EN 50581, EN 62321

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Place and date of issue

Malene Giese Jakobsen

Global Regulatory Affairs

Malene Giese Jakobsen