

EC Declaration of Conformity

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

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

Brand: **Widex**
 Series: **ENJOY**
 Description: **Hearing Aid**

Model	Variant(s)		Type	GMDN code	GMDN Term
E-FA	T-VC-RC	-, 30, 50, 100, 110, 220, 330, 440	BTE	34671	Behind-the-ear air-conduction hearing aid
E-FP	T-VC-RC	-, 30, 50, 100, 110, 220, 330, 440			
E-FM	RC	-, 30, 50, 100, 110, 220, 330, 440			
EBB3D	T-RC-BTE 13 D	-, 50, 100, 110, 220, 330, 440			
E-PA	RC	-, 100, 110, 220, 330, 440	RIC	47169	Receiver-in-canal air-conduction hearing aid
E-F2	T-RC, T-RC-Z	-, 50, 100, 110, 220, 330, 440	RIC, RITE		
E-FS	T-RC, T-RC-Z	-, 50, 100, 110, 220, 330, 440			
E-XP	T-RC	-, 30, 50, 100, 110, 220, 330, 440	ITE	34672	In-the-ear air-conduction hearing aid
E-IM	L, R	-, 110, 220, 330, 440			
E-IP	L, R	-, 110, 220, 330, 440			
E-CIC	RC-R, RC-L	-, 50, 100, 110, 220, 330, 440	CIC	41209	Canal air-conduction hearing aid
E-CIC TR	RC-R, RC-L	-, 50, 100, 110, 220, 330, 440			
E-CIC M	N/A	-, 50, 100, 110, 220, 330, 440			
E-CIC-M TR	N/A	-, 50, 100, 110, 220, 330, 440			

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 2014/53/EU (RED)
Directive 2011/65/EU (RoHS 2)

Conformity assessment procedure	MDD : Annex II of 93/42/EEC RED : Annex II of 2014/53/EU
Notified Body	MDD : TÜV SÜD Product Service GmbH, Notified Body No.: NB 0123 Ridlerstr. 65, 80339 München, Germany
EC-Certificate	MDD : No. G1 093461 0011
Classification of Device	MDD : Class IIa, Rule 9 according to 93/42/EEC Annex IX
Applied standards and specifications in conformity assessment.	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 62304, EN 62366-1, EN 60601-2-66
Standard versions valid on the date when this DoC is issued.	RED : EN 60950-1, EN 62479, EN 301 489-1, EN 301 489-3, EN 301 489-17, EN 300 330, EN 300 328, EN 300 422-4 RoHS 2 : EN 50581, EN 62321
Technical File is held by	Widex A/S, Nymoellevej 6, DK-3540 Lyngø, Denmark

Lyngø, 24-09-2020

Place and date of issue


 Senior Director, Global Regulatory Affairs Kristine Klitgaard Pedersen