

# 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: **UNIQUE**  
 Description: **Hearing Aid**

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

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 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 300 330, 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