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: Acuitis
Description: Hearing Aid

Model	Variant(s)	Type	GMDN code	GMDN Term
AFA D	T-VC-RC	BTE	34671	Behind-the-ear air-conduction hearing aid
AFA E	T-VC-RC			
AFP E	T-VC-RC			
AFM U	RC			
AFM E	RC			
APA D	RC	RIC	47169	Receiver-in-canal air-conduction hearing aid
APA U	RC			
APA E	RC			
AERB0	RC-RIC 10			
AFS D	T-RC	RIC, RITE		
AFS U	T-RC			
AFS E	T-RC, T-RC-Z			
AF2 B	T-RC			
AF2 E	T-RC, T-RC-Z			
AXP E	T-RC	ITE	34672	In-the-ear air-conduction hearing aid
AIM E	L, R			
AIP E	L, R			
ACIC D	RC-R, RC-L	CIC	41209	Canal air-conduction hearing aid
ACIC U	RC-R, RC-L			
ACIC E	RC-R, RC-L			
ACIC D TR	RC-R, RC-L			
ACIC U TR	RC-R, RC-L			
ACIC E TR	RC-R, RC-L			
ACICM D	N/A			
ACICM U				
ACICM E				
ACICM D TR				
ACICM U TR				
ACICM E TR				

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 : 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 RED : EN 60950-1, EN 62479, EN 301 489-1, EN 301 489-3, EN 301 489-17, EN 300 330 RoHS 2 : EN 50581, EN 62321
Technical File is held by	Widex A/S, Nymoellevej 6, DK-3540 Lynge, Denmark

Lynge, 16 August 2019
Place and date of issue

Regulatory Affairs Specialist — Kathrine Søby