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: EVOKE
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			
EBB3D	T-RC-BTE 13 D	-, 110,220,330,440			
E-FM	RC	-, 30,50,100,110,220,330,440			
E-PA	RC	-, 110,220,330,440	RIC	47169	Receiver-in-canal air-conduction hearing aid
ERB0	RC-RIC 10	-, 100,110,220,330,440			
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			
ERB2D	T-RC-RIC 312 D, T-RC-Z-RIC 312 D	-, 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 : 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 62304, EN 62366-1, EN 60601-2-66 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 Lynge, Denmark

Lynge, 11-09-2019
Place and date of issue

Global Regulatory Affairs

Kathrine Søby