

EU DECLARATION OF CONFORMITY

Manufacturer: **Widex A/S**
Nymoellevej 6
DK-3540 Lyngø
Denmark

Brand: **Widex**
Product Family: **EVOKE**
Type of Device: **Hearing Aids**
Basic UDI-DI: **N/A**
Single registration number: **N/A**
GMDN Code: **See next page**
Product Identification: **See next page**

We declare under our sole responsibility that above products are in conformity with the following Directives:

Council Directive 93/42/EEC as amended by Dir. 2007/47/EC (MDD)

Conformity assessment procedure: **Annex II of 93/42/EEC**
Notified Body: **TÜV SÜD Product Service GmbH, Notified Body No.: NB 0123
Ridlerstr. 65, 80339 München, Germany**
Classification of device: **Class IIa, Rule 9 according to 93/42/EEC Annex IX**

The products meet all applicable standards and the general safety and performance requirements of the Directive Annex II of 93/42/EEC. Applicable standards are listed in the respective technical file.

Council Directive 2011/65/EU (RoHS)

Relevant Harmonized Standards: **EN 50581, EN 62321**

Council Directive 2014/53/EU (RED)

Relevant Harmonized Standards: **EN 60950-1, EN 62479, EN 301 489-1, EN 301 489-3, EN 301 489-17,
Standard versions valid on the date **EN 300 330, EN 300 328, EN 300 422-4**
when this DoC is issued.**

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Product Identification			Type of Device		
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	-, 50,100,110,220,330,440			
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	-, 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			

This Declaration of Conformity includes all hearing aid components and spare parts of the products listed above.

Place and valid from date Lyngø, September 8, 2020

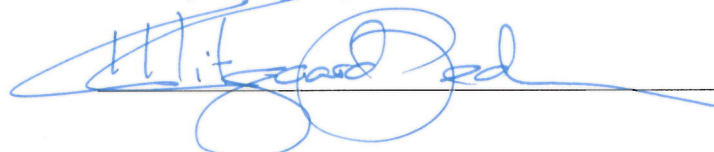


Name

Hans-Otto Bindeballe

Global Regulatory Affairs Manager

Signature



This declaration will be renewed on any significant change of product, product range, standards and laws.