

# 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:

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**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.

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**Council Directive 2011/65/EU (RoHS)**

Relevant Harmonized Standards: EN 50581, EN 62321

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**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, 110 DEMO, 220, 220 DEMO,330, 330 DEMO ,440, 440 DEMO	BTE	34671	Behind-the-ear air-conduction hearing aid
E-FP	T-VC-RC	-,30,50,100,110, 110 DEMO, 220, 220 DEMO,330, 330 DEMO ,440, 440 DEMO			
EBB3D	T-RC-BTE 13 D	-,50,100,110, 110 DEMO, 220, 220 DEMO,330, 330 DEMO ,440, 440 DEMO			
E-FM	RC	-,30,50,100,110, 110 DEMO, 220, 220 DEMO,330, 330 DEMO ,440, 440 DEMO			
E-PA	RC	-,110, 110 DEMO, 220, 220 DEMO,330, 330 DEMO ,440, 440 DEMO	RIC	47169	Receiver-in-canal-air-conduction hearing aid
ERB0	RC-RIC 10	-,110, 110 DEMO, 220, 220 DEMO,330, 330 DEMO ,440, 440 DEMO			
E-F2	T-RC, T-RC-Z	-,50,100,110, 110 DEMO, 220, 220 DEMO,330, 330 DEMO ,440, 440 DEMO	RIC, RITE	47169	Receiver-in-canal-air-conduction hearing aid
E-FS	T-RC, T-RC-Z	-,50,100,110, 110 DEMO, 220, 220 DEMO,330, 330 DEMO ,440, 440 DEMO			
ERB2D	T-RC-RIC 312 D, T-RC-Z-RIC 312 D	-,110, 110 DEMO, 220, 220 DEMO,330, 330 DEMO ,440, 440 DEMO			
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

Lynge, April 27, 2021

Name

Malene Giese Jakobsen

Senior Regulatory Affairs Specialist

Signature



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