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

Series: REGAL, REGAL 2
Description: Hearing Aid

Series	Model	Variant(s)	Type	GMDN code	GMDN Term
REGAL	D-FS	T-RC	RIC, RITE	47169	Receiver-in-canal air-conduction hearing aid
REGAL 2	U-FS	T-RC	RIC, RITE	47169	Receiver-in-canal air-conduction hearing aid

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 R&TTE : Annex III of 2014/53/EU
Notified Body	MDD : TÜV SÜD Product Service GmbH, Notified Body No.: NB 0123 Ridlerstr. 57, 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. Standard versions valid on the date when this DoC is issued.	MDD : EN 1041, EN 10993-1, EN 10993-5, EN 10993-10, EN 10993-12, EN 10993-18, 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 60601-1-6, EN 62304, EN 62366 R&TTE : EN 60950-1, EN 62479, EN 301 489-1, EN 301 489-3, EN 300 330-2 RoHS 2 : EN 50581, EN 62321

Lynge, 16-06-2020
Place and date of issue

Director, Global Regulatory Affairs — Kristine Klitgaard Pedersen