

EU DECLARATION OF CONFORMITY

Manufacturer	WSAUD A/S Nymoellevej 6 DK-3540 Lyngbe Denmark
Brand:	Rexton
Product Family:	BiCore B M
Type of Device:	Hearing Aids
Basic UDI-DI:	5714880-WSA-26-10-3J
Single registration number:	DK-MF-000015974
GMDN Code:	34671 Behind-the-ear airconduction hearing aid
EMDN Code:	Y2145060101 BEHIND-THE-EAR HEARING AIDS WITH RECEIVER IN THE DEVICE (BTE)
Product Identification:	See next page(s)

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

REGULATION (EU) 2017/745 (MDR) OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

Conformity assessment procedure:	Annex IX of Regulation (EU) 2017/745
Notified Body:	TÜV SÜD Product Service GmbH, Notified Body No.: NB 0123 Ridlerstr. 65, 80339 München, Germany
EC certificate (valid at ver. 1 of this Declaration of Conformity):	EC certificate number: G10 105767 0002
Classification of device:	Class IIa (according to Annex VIII Rule 9 to Regulation (EU) 2017/745)

The products meet all applicable standards and the general safety and performance requirements of the Regulation (EU) 2017/745 Annex I. Applicable standards are listed in the respective technical documentation.

Council Directive 2011/65/EU (RoHS) as amended by Dir. 2017/2102/EC (RoHS2)

Relevant Harmonized Standards:	EN IEC 63000
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Council Directive 2014/53/EU (RED)

Relevant Standards:	EN 300 330, EN 300 328, EN 300 422-4
Standard versions as listed in the respective technical documentation	EN 62311, EN 62479, EN 301 489-3, EN 301 489-1, EN 301 489-17

EU DECLARATION OF CONFORMITY

Council Directive 2014/34/EU (ATEX)

Notified Body: Danish Technological Institute Dancert A/S
Gregersensvej 1, DK-2630 Taastrup, Denmark

Notified Body No.: 1073

Assessed the EU-type examination
set out in Annex III

Certificate number: DTI 23ATEX0278X ver.01

Scope of ATEX protection and
examination scope:

II 2G Ex ia IIC T6 Gb

I M2 Ex ia I Mb

II 2D Ex ia IIIC T60°C Db

Notified Body

DEKRA Testing and Certification GmbH
Handwerkstraße 15, 70565 Stuttgart, Germany

Notified Body No.: 0158

Assessed the conformity to type
based on product quality assurance
set out in Annex VII

Notification number: BVS 24 ATEX ZQS/E455

Relevant Harmonized Standards:

EN IEC 60079-0, EN 60079-11

Standard versions as listed in the
respective technical documentation

Note:

Declaration of Conformity is only valid together with the product ATEX
supplement and ATEX Safety Card

Products that comply to ATEX is indicated below table with an ^

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Product Identification	Type of Device
BiCore B M 80	BTE (Behind The Ear) Hearing Aid including earmoulds
BiCore B M 60	
BiCore B M 40	
^ BiCore B M 30	
^ BiCore B M 20	
^ BiCore B M 10	
^ BiCore B M SDemo	

This Declaration of Conformity includes all hearing aid components and spare parts like earmold, or hooks of the products listed above.

Place and valid from date

Singapore, 13 March 2025

Name & Signature

(Regulatory Affairs Manager)

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