

EU DECLARATION OF CONFORMITY

Manufacturer: **WSAUD A/S**
Nymoellevej 6
DK-3540 Lynge
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: No. G10 105767 0002 Rev. 00
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

Council Directive 2014/53/EU (RED)

Relevant Harmonized Standards: EN 62311, EN 62479, EN 301 489-1, EN 301 489-3, EN 301 489-17, EN 300 330, EN 300 328, EN 300 422-4

Standard versions as listed in the respective technical documentation



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Product Identification	Type of Device
BiCore B M 30	BTE (Behind The Ear) Hearing Aid including earmoulds
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, 5 January 2023

Name Khoo Choon Mong
Regulatory Affairs Manager

Signature

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