EU DECLARATION OF CONFORMITY

Manufacturer	**WSAUD A/S** Nymoellevej 6 DK-3540 Lynge Denmark
Brand:	**Signia**
Product Family:	Pure C&G BCT IX RIC
Type of Device:	Hearing Aids
Basic UDI-DI:	5714880-WSA-29-15-52
Single registration number:	DK-MF-000015974
GMDN Code:	47169 Air-conduction hearing aid, receiver-in-canal
	59460 Contralateral hearing unit (CROS)
EMDN Code:	Y2145060102 BEHIND-THE-EAR HEARING AIDS WITH RECEIVER IN THE CANAL (RIC, RITE)
	Y214599 HEARING AIDS - OTHER
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 Rev. 01
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

Product Identification	Type of Device
Pure C&G BCT 7IX Pure C&G BCT 5IX Pure C&G BCT 3IX Pure C&G BCT sDemo DIX	**RIC (Receiver In the Canal) Hearing Aid**
CROS Pure C&G BCT IX	**Contralateral hearing unit (CROS)** CROS/BiCROS system used together with compatible hearing aids as a system

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, 19 February 2025
Name	Khoo Choon Mong (Regulatory Affairs Manager)
Signature	Khoo, Choon Mong (AU000N1Z) Digitally signed by Khoo, Choon Mong (AU000N1Z) Date: 2025.02.19 15:58:26 +08'00'

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