EU DECLARATION OF CONFORMITY

Manufacturer	**WSAUD A/S** Nymoellevej 6 DK-3540 Lynge Denmark
Brand:	**Signia**
Product Family:	Pure C&G IX
Type of Device:	Hearing Aids
Basic UDI-DI:	5714880-WSA-28-15-4P
Single registration number:	DK-MF-000015974
GMDN Code:	47169 Receiver-in-canal air-conduction hearing aid
	59460 Contralateral hearing unit
EMDN Code:	Y2145060102 BEHIND-THE-EAR HEARING AIDS WITH RECEIVER IN THE CANAL (RIC, RITE)
	Y214599 HEARING AIDS - OTHER
Product Identification:	See next page

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 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: Standard versions as listed in the respective technical documentation	EN 300 330, EN 300 328
Other Relevant Standards	EN 62311, EN 62479, EN 301 489-3, EN 301 489-1, EN 301 489-17, 300 422-4 *(only relevant to Pure C&G T IX)*

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Product Identification	Type of Device
Pure C&G T 7IX Pure C&G T 5IX Pure C&G T 3IX Pure C&G T 2IX Pure C&G T 1IX Pure C&G T sDemo DIX	**RIC (Receiver In the Canal) Hearing Aid**
Pure C&G 7IX Pure C&G 5IX Pure C&G 3IX Pure C&G 2IX Pure C&G 1IX Pure C&G sDemo DIX	
CROS Pure C&G 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: Lynge, 22 February 2024

Name: Marcin Karwowski
Regulatory Affairs Manager

Signature: Karwowski, Marcin (AU00115B) Digitally signed by Karwowski, Marcin (AU00115B) Date: 2024.02.22 14:27:01 +01'00'

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