



EU DECLARATION OF CONFORMITY

Manufacturer: **WSAUD A/S**
Nymoellevej 6
DK-3540 Lynge
Denmark

Single registration number: DK-MF-000015974

Brand: **Signia**

Product Family: PURE C&G MAX

Type of Device: Hearing Aids

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: 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:

Standard versions as listed in the respective technical documentation: EN IEC 63000

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



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Product Identification	Type of Device	GMDN code	EMDN code	Basic UDI-DI
Pure C&G MaX 7 Pure C&G MaX 5 Pure C&G MaX 3 Pure C&G MaX 2 Pure C&G MaX 1 Pure C&G MaX sDemo D	RIC (Receiver In the Canal) Hearing Aid including earmoulds	47169 Receiver-in-canal air-conduction hearing aid	Y2145060102 BEHIND-THE-EAR HEARING AIDS WITH RECEIVER IN THE CANAL (RIC, RITE)	5714880-WSA-31-15-2P

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

On behalf of WSAUD A/S

Name

Klaus Andersen

Regulatory Affairs Specialist

Signature

Valid from date

Place

Lynge

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