EU DECLARATION OF CONFORMITY

Manufacturer	**WSAUD A/S** Nymoellevej 6 DK-3540 Lynge Denmark
Brand:	Signia
Product Family:	Active IX
Type of Device:	Hearing Aids
Basic UDI-DI:	5714880-WSA-28-30-4J
Single registration number:	DK-MF-00001597
GMDN Code:	34672 In-the-ear air-conduction hearing aid
	59460 Contralateral hearing unit
EMDN Code:	Y2145060202 HEARING AIDS IN-THE-CANAL (ITC)
	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 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
	EN 62311, EN 62479, EN 301 489-3, EN 301 489-1, EN 301 489-17
Other Relevant Standards	

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Product Identification	Type of Device
Active Pro IX Active IX Active sDEMO DIX	**ITE (In The Ear) Hearing Aid including faceplate***
Kit Active Pro IX Kit Active IX Kit Active sDEMO DIX	**ITE (In The Ear) Hearing Aid including faceplate* & Charger for hearing instruments**
CROS Active 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, April 25, 2024

Name: Marcin Karwowski
Regulatory Affairs Manager

Signature: Karwowski, Marcin (AU00115B) Digitally signed by Karwowski, Marcin (AU00115B) Date: 2024.04.25 11:33:51 +02'00'

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

*A Custom made Faceplate [CFPS] is an integral component of the final Product(s) mentioned on this declaration of conformity.
The configurable variants where CFPS can be made off, are part of the Design Review release process of the Product.