



EU DECLARATION OF CONFORMITY

Manufacturer	WSAUD A/S Nymoellevej 6 DK-3540 Lyngø Denmark
Brand	Signia
Product Family:	INSIO IX
Type of Device:	Hearing Aids
Basic UDI-DI:	5714880-WSA-26-25-46
Single registration number:	DK-MF-000015974
GMDN Code:	34672 In-the-ear airconduction hearing aid
EMDN Code:	Y21450602 IN-THE-EAR HEARING AIDS (ITEs)
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
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Council Directive 2014/53/EU (RED)

Relevant Harmonized Standards:	EN 300 330
Standard versions as listed in the respective technical documentation	
Other Relevant Standards	EN 62311, EN 62479, EN 301 489-3, EN 301 489-1

