

## **EU DECLARATION OF CONFORMITY**

Manufacturer	<b>WSAUD A/S</b> Nymoellevej 6 DK-3540 Lynge Denmark
Brand:	Signia
Product Family:	Intuis 4
Type of Device:	Hearing Aids
Basic UDI-DI:	5714880-WSA-26-10-3J
Single registration number:	DK-MF-000015974
GMDN Code:	34671 Behind-the-ear air-conduction hearing aid
EMDN Code:	Y2145060101 BEHIND-THE-EAR HEARING AIDS WITH RECEIVER IN THE DEVICE (BTE)
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 class IIa products
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 most all applicable stand	and and the general selectly and performance requirements of the

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 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



## **EU DECLARATION OF CONFORMITY**

Product Identification	Type of Device
Intuis SP 4.7	BTE (Behind The Ear) Hearing Aid
Intuis SP 4.5	including earmoulds
Intuis SP 4.3	
Intuis SP 4.2	
Intuis SP 4.1	
Intuis SP 4.0	
Intuis SP 4.D sDemo	
Intuis P 4.7	
Intuis P 4.5	
Intuis P 4.3	
Intuis P 4.2	
Intuis P 4.1	
Intuis P 4.0	
Intuis P 4.D sDemo	
Intuis M 4.7	
Intuis M 4.5	
Intuis M 4.3	
Intuis M 4.2	
Intuis M 4.1	
Intuis M 4.0	
Intuis M 4.D sDemo	

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, August 28, 2024

Name

Marcin Karwowski

Regulatory Affairs Manager

Signature

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