



EU DECLARATION OF CONFORMITY

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

Brand: **Signia**

Product Family: **Styletto IX**

Type of Device: **Hearing Aids**

Basic UDI-DI: **5714880-WSA-28-17-4V**

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(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: **EN 300 330, EN 300 328**

Standard versions as listed in the respective technical documentation

Other Relevant Standards **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
Styletto 7IX Styletto 5IX Styletto 3IX Styletto sDemo DIX	RIC (Receiver In the Canal) Hearing Aid
KIT Styletto 7IX KIT Styletto 5IX KIT Styletto 3IX KIT Styletto sDemo DIX	
CROS Styletto 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, February 26, 2024

Name Marcin Karwowski
Regulatory Affairs Manager

Signature

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