



EU DECLARATION OF CONFORMITY

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

Brand: **Signia**

Product Family: **Stretta**

Type of Device: **Hearing Aids**

Basic UDI-DI: **5714880-WSA-21-10-ZQ**

GMDN Code: **34671 Behind-the-ear air-conduction hearing aid**

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**

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: **EN62321**

Council Directive 2014/53/EU (RED)

Relevant Harmonized Standards: **EN 62479, EN 301 489-1, EN 301 489-3, EN 301 489-17, EN 300 330,
EN 300 328, EN 300 422-4**

Standard versions valid on the date when this DoC is issued.



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Product Identification	Type of Device
Stretta M Stretta HP	BTE (Behind The Ear) Hearing Aid including earmoulds

This Declaration of Conformity includes all hearing aid components and spare parts of the products listed above.

Place and valid from date Lynge, August 26, 2021

Name Malene Giese Jakobsen
Senior Regulatory Affairs Specialist

Signature *Malene Giese Jakobsen*

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