

EU DECLARATION OF CONFORMITY

Manufacturer WSAUD A/S

Nymoellevej 6 DK-3540 Lynge 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,

Standard versions valid on the date EN 300 328, EN 300 422-4

when this DoC is issued.



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Type of Device
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

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