

EU DECLARATION OF CONFORMITY

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

Private Label Name: **advance**

Product Family: **M-Core B-Li**

Type of Device: **Hearing Aids**

Basic UDI-DI: **5714880-WSA-25-10-37**

GMDN Code: **34671 Behind-the-ear airconduction 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 301 489-1, EN 301 489-3, EN 301 489-17, EN 300 330, EN 300 328,**

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

Product Identification	Type of Device
OTE LI 819 OTE LI 619 OTE LI 419 OTE LI 319 OTE LI 219	BTE (Behind The Ear) Hearing Aid including earmoulds
P LI 819 P LI 619 P LI 419 P LI 319 P LI 219	BTE (Behind The Ear) Hearing Aid including earmoulds
SP LI 819	BTE (Behind The Ear) Hearing Aid

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SP LI 619 SP LI 419 SP LI 319 SP LI 219	including earmoulds
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This Declaration of Conformity includes all hearing aid components and spare parts of the products listed above.

Place and valid from date Lyngø, April 06, 2021

Name Malene Giese Jakobsen

Sr. Regulatory Affairs Specialist

Signature *Malene Giese Jakobsen*

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