

EU DECLARATION OF CONFORMITY

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

Private Label: **SoniTon**

Product Family: LI-ION G6

Type of Device: Hearing Aids

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

Single registration number: N/A

GMDN Code: 34671 Behind-the-ear airconduction hearing aid

Product Identification: See below

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
HdO 13 Li P 6.4 HdO 13 Li DUO 6.4 HdO 13 Li DUO 6.6	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.

