

EU DECLARATION OF CONFORMITY

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

Brand: **Connexx**

Product Family: Smart Connect

Type of Device: Accessory for Hearing Aids

Basic UDI-DI: 5714880-WSA-19-54-56

GMDN Code: 57884 Hearing aid wireless-fitting computer aided set

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

Classification of device: **Class I** (according to Annex VIII Rule 13 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 50581:2012

Council Directive 2014/53/EU (RED)

Relevant Harmonized Standards: EN 301 489-3 v.1.6.1, EN 300 330 v2.1.1

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

Product Identification	Type of Device
Smart Connect	Accessory for Hearing Aids

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

Place and valid from date: Lyngbe, February 10, 2021

Name: Hans-Otto Bindeballe
 Global Regulatory Affairs Manager

Signature: 

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