

EU DECLARATION OF CONFORMITY

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

Product Family: **CONNEXX**

Type of Device: **Software**

Basic UDI-DI: **5714880-WSA-80-45-4U**

GMDN Code: **60211 Audiometric/hearing device software**

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 11, Annex VIII Chapter II 3.3 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:

| Product Identification | Type of Device |
|------------------------|----------------------------------|
| CONNEXX 9.5 | Software for hearing aids |
| SiFit 9.5 | Hearing aid database for CONNEXX |
| ViOFit 9.5 | Hearing aid database for CONNEXX |
| MikiFit 9.5 | Hearing aid database for CONNEXX |
| NHSFit 9.5 | Hearing aid database for CONNEXX |

Place and valid from date **Lyngø, February 25, 2021**

Name **Malene Giese Jakobsen**
Sr. Regulatory Affairs Specialist

Signature



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