

EU DECLARATION OF CONFORMITY

MANUFACTURER

WSAUD A/S
NYMOELLEVEJ 6
DK-3540 LYNGE
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 Regulation:

Council Regulation 2017/745 (MDR)

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 9.4	Software for hearing aids

Product Identification	Type of Device
SiFit 9.4	Hearing aid database for CONNEXX
RexFit 9.4	Hearing aid database for CONNEXX

Place and valid from date: Lynge 2020-12-10

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.