

EU DECLARATION OF CONFORMITY

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

Brand: **Coselgi**

Product Family: **C-Tune II**

Type of Device: **Hearing aid fitting software**

Basic UDI-DI: **5706069-WSA-CTUNEII**

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

Product Identification: **See next page**

We declare under our sole responsibility that above products are in conformity with the following Regulation:

Council Regulation 2017/745 (MDR)

For medical products

Conformity assessment procedure: **Annex IX of Regulation (EU) 2017/745**

Notified Body: **TÜV SÜD Product Service GmbH, Notified Body No.: NB 0123
Ridlerstr. 57, 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 file.

Product Identification	Type of Device
C-Tune II	Fitting software

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

Place and valid from date: **Lyngbe, August 11, 2020**

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.