

EU DECLARATION OF CONFORMITY

Manufacturer

WSAUD A/S

Nymoellevej 6 DK-3540 Lynge Denmark

Brand:

WIDEX

Product Family:

WIDEX CROS DEVICES

Type of Device:

CROS audio streaming device

Basic UDI-DI:

5714880-WSA-24-15-SW

GMDN Code:

59460 Contralateral hearing unit

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:

EN50531, EN62321

Council Directive 2014/53/EU (RED)

Relevant Harmonized Standards:

Standard versions valid on the date

when this DoC is issued.

EN 62479, EN 301 489-1, EN 301 489-3, EN 300 330

| Product Identification | Type of Device |
|------------------------|-----------------------------|
| CROS-FS | CROS audio streaming device |

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

Place and valid from date

Lynge, February 04, 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.

Document Number: DoC_Widex_CROS-FS - Version: 1.0 - page 1 of 1

Template: GLOBAL_F_DOC_050 - version: 11.0 - effective: 2021-01-01