

EU DECLARATION OF CONFORMITY

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

Brand: **WIDEX**

Product Family: Earmolds

Type of Device: Earmolds for Hearing Aids

Basic UDI-DI: 5714880-WSA-80-80-4Z

GMDN Code: 62259 Earmould, preformed

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

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 5 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
Ear Mold	Soft Mold Hard Mold Click Mold

This Declaration of Conformity includes all hearing aid components and spare parts like earmold, or hooks of the products listed above.

Place and valid from date: Lyngø, October 27, 2021

Name: Malene Giese Jakobsen
Senior Regulatory Affairs Specialist

Signature: *Malene Giese Jakobsen*

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