

EU DECLARATION OF CONFORMITY

Manufacturer	WSAUD A/S Nymoellevej 6 DK-3540 Lyngø Denmark
Private Label Name:	ViO Kollektion
Product Family:	ViO
Type of Device:	Hearing Aids
Basic UDI-DI:	4063006-SIG-24-15-SW
Single registration number:	N/A
GMDN Code:	34671
Product Identification:	See next page(s)

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 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 documentation.

Council Directive 2011/65/EU (RoHS) as amended by Dir. 2017/2102/EC (RoHS2)

Relevant Harmonized Standards:	EN 50581, EN62321
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Council Directive 2014/53/EU (RED)

Relevant Harmonized Standards:	EN 301 489-1, EN 301 489-3, EN 301 489-17, EN 300 330, EN 300 328,
Standard versions valid on the date when this DoC is issued.	EN 300 422-4

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Product Identification	Type of Device
ViO E428 LI ViO E328 LI ViO E228 LI ViO E138 LI ViO Ed28 LI	BTE (Behind The Ear) Hearing Aid including earmoulds
ViO E429 LI ViO E329 LI ViO E229 LI ViO E139 LI	

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

Place and valid from date

Lynge, February 01, 2021

Name

Malene Giese Jakobsen

Sr. Regulatory Affairs Specialist

Signature

Malene Giese Jakobsen

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