European Declaration of Conformity
to the Medical Regulation (EU) MDR 2017/745

CE
0483

Manufacturers Name:	Oscilla A/S
Manufacturers Address:	Aabogade 15, 8200 Aarhus, DENMARK
SRN (Single Registration Number):	DK-MF-000002784

Name of the Device (s):	Oscilla® A30, Oscilla® A50, Oscilla® A60(ATM4)
Product family (DMR):	ATM4
Intended Use:	Diagnostic audiometric testing.
Basic UDI-DI:	5745000311ATM4TW
Classification & Rule:	IIa: EC conformity declaration according to Annex VIII, Chapter III, Rule 10, sub-rule 1 of Regulation (EU) 2017/745

Name of the MDSW :	Oscilla® AudioConsole® 4.5.0 (SW01)
Product family (DMR):	SW01 rev. 4.5.0
Intended Use:	Software user interface for audiometric medical devices.
Basic UDI-DI:	5745000311SW01VH
Classification & Rule:	IIa: EC conformity declaration according to Annex VIII Chapter II section 3.3 & according to Annex VIII, Chapter III, Rule 11 of Regulation (EU) 2017/745

Medical devices:	See Appendix A
Technical Standards and Common Specifications:	See Appendix B
Notified Body name:	MDC medical device certification GmbH
Notified Body Address:	Kriegerstraße 6 70191 Stuttgart, Deutschland
Notified Body Identification number:	0483
Conformity assessment procedure followed:	MDR 2017/745 Annex IX, Conformity assessment based on a quality management system and assessment of the technical documentation.
MDR EU 2017/745 certificate registration No:	D1492000001

This declaration of conformity is issued under the sole responsibility of Oscilla A/S. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval to ISO 13485 issued by MDC medical device certification GmbH.
All supporting documentation is retained at the premises of the manufacturer.

Signature:

Joachim Boll, CEO & Partner for Oscilla A/S

Place and date (yyyy-mm- dd) of issue:

Aarhus, Denmark 2025-01-10

Certified Quality System ISO 13485 mdc

EUDAMED European Database for Medical Devices

EU-MDR

MADE IN DENMARK

Appendix A: Medical devices

#	UDI-DI	Description	REF.	Class [Rule]	Intended use	Basic UDI-DI (GMN) [Platform]	GMDN/CND	Manufacture
1	05745000311156	Oscilla® A30 w. DD65 headset	1230	IIa [Annex VIII, Chapter III, Rule 10, sub-rule 1 of (EU) 2017/745]	Diagnostic audiometric testing.	5745000311ATM4TW [ATM4]	GMDN: 37503 Tone audiometer GMDN 41188, Speech audiometer CND: Z121401 (Audiometer)	Oscilla A/S Aabogade 15 8200 Aarhus, DENMARK
2	05745000311163	Oscilla® A30 w. H210A headset	1231					
3	05745000311170	Oscilla® A50 w. DD65 headset	1233					
4	05745000311187	Oscilla® A50 w. H210A headset	1235					
5	05745000311194	Oscilla® A60 w. DD65 headset	1237					
6	05745000311200	Oscilla® A60 w. H210A headset	1239					
7	05745000311033	Oscilla® AudioConsole® PC software	1218	IIa [The SW01 is classified as Class IIa device software according to Annex VIII Chapter II section 3.3 & according to Annex VIII, Chapter III, Rule 11 of Regulation (EU) 2017/745]	Software user interface for audiometric medical devices.	5745000311SW01VH [SW01]	Medical Device Software (MDSW) GMDN 60211 Audiometric device software	

Appendix B: Technical Standards and Common Specifications

#	Standard number	Standard name
1	EN 60601-1:2006+A1+A12+A2+A13:2024 IEC 60601-1:2005/A1:2012 (Edition 3.1)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2	EN 60601-1-2:2015/A1:2021 IEC 60601-1-2:2014+AMD1:2020	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
3	EN 60601-1-6:2010/A2:2021 IEC 60601-1-6:2010 +AMD1:2013+AMD2:2020	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
4	EN 60645-1:2017 IEC 60645-1:2017	Electroacoustics - Audiometric equipment - Part 1: Equipment for pure-tone and speech audiometry
5	EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
6	EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
7	IEC 62366-1:2015 /A1:2020	Medical devices - Application of usability engineering to medical devices
8	EN 62304:2006/A1:2015 IEC 62304:2006/AMD 1:2015	Medical device software - Software life-cycle processes
9	EN ISO 10993-1:2020 (EN ISO 10993-1-5:2009, EN ISO 10993-10:2010, EN ISO 10993-12:2021, EN ISO 10993-23:2021, EN ISO 10993-18:2020, ISO/TS 10993-19:2020)	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
10	ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
11	EN ISO 20417:2021	- Medical devices - Information to be supplied by the manufacturer
12	ISO 389-8:2004	Acoustics — Reference zero for the calibration of audiometric equipment — Part 8: Reference equivalent threshold sound pressure levels for pure tones and circumaural earphones
13	ISO 389-3: 2016	Acoustics — Reference zero for the calibration of audiometric equipment — Part 3: Reference equivalent threshold vibratory force levels for pure tones and bone vibrators
14	ANSI/ASA S3.7-2016	Method For Measurement And Calibration Of Earphones
15	ANSI/ASA S3.6-2018	Specification For Audiometers