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 rev. 04
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® 4.4.0 (SW01)
Product family (DMR):	SW01 rev. 4.4.0.335
Intended Use:	Software user interface for audiometric medical devices. 5745000311SW01VH
Basic UDI-DI:	IIa: EC conformity declaration according to Annex VIII Chapter II section 3.3 &
Classification & Rule:	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:	
Notified Body Address:	MDC medical device certification GmbH
Notified Body Identification number:	Kriegerstraße 6 70191 Stuttgart, Deutschland 0483
Conformity assessment procedure followed:	MDR 2017/745 Annex IX, Conformity assessment based on a quality management system and assessment of the technical documentation.

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 2022-03-21

Certified Quality System ISO 13485 mdc

EUDAMED European Database for Medical Devices

EU-MDR

MADE IN DENMARK

Appendix A: Medical devices

#	UDI-DI	Description	Class [Rule]	Intended use	Basic UDI-DI (GMN) [Platform]	GMDN/CND	Manufacture
1	05745000311156	Oscilla® A30 w. DD65 headset	IIa [Annex VIII, Chapter III, Rule 10, sub-rule 1 of (EU) 2017/745]	Diagnostic audiometric testing.	5745000311ATM4TW [ATM4]	GMDN: 41184, Tone audiometer, manual 41185, Tone audiometer, semi-automated 41188, Speech audiometer CND: Z121401 (Audiometer)	Oscilla A/S Aabogade 15 8200 Aarhus, DENMARK
2	05745000311163	Oscilla® A30 w. H210A headset					
3	05745000311170	Oscilla® A50 w. DD65 headset					
4	05745000311187	Oscilla® A50 w. H210A headset					
5	05745000311194	Oscilla® A60 w. DD65 headset					
6	05745000311200	Oscilla® A60 w. H210A headset					
7	05745000311033	Oscilla® AudioConsole® PC software	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)	

Appendix B: Technical Standards and Common Specifications

#	Standard number	Standard name
1	EN 60601-1:2006/A1:2013 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 60601-1-4:1996 IEC 60601-1-4:1996 IEC 60601-1-4:1996/A1:1999	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems
4	EN 60601-1-6:2010/A1:2015 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
5	EN 60645-1:2017 IEC 60645-1:2017	Electroacoustics - Audiometric equipment - Part 1: Equipment for pure-tone and speech audiometry
6	EN ISO 13485:2016 + EN ISO 13485:2016/AC:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
7	EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
8	IEC 62366-1:2015	Medical devices - Application of usability engineering to medical devices
9	EN 62304:2006/A1:2015 IEC 62304:2006/AMD 1:2015	Medical device software - Software life-cycle processes
10	EN ISO 10993-1:2009 + EN ISO 10993-1:2009/AC:2010 ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
11	ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
12	EN ISO 20417:2021	- Medical devices - Information to be supplied by the manufacturer
13	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
14	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