



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



**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® 4.4.0 (SW01)  
**Product family (DMR):** SW01 rev. 4.4.0  
**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.

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 2024-02-29



## 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	Ila [Annex VIII, Chapter III, Rule 10, sub-rule 1 of (EU) 2017/745]	Diagnostic audiometric testing.	5745000311ATM4TW [ATM4]	GMDN: 37503 Tone 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	Ila [The SW01 is classified as Class Ila 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/A1:2013/A2:2021 /AC:2023 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/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
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/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
7	EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
8	IEC 62366-1:2015 /A1:2020	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 10993-1:2020 (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
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
15	ANSI/ASA S3.7-2016	Method For Measurement And Calibration Of Earphones
16	ANSI/ASA S3.6-2018	Specification For Audiometers