



Declaration according Article 22 of Regulation (EU) 2017745

Systems and procedure packs



Manufacturers Name:	Oscilla A/S
Manufacturers Address:	Aabogade 15, 8200 Aarhus, DENMARK
SRN (Manufacture):	DK-MF-000002784
SRN (Systems and procedure packs):	DK-PR-000045114
Basic UDI-DI:	5745000311ATM4TW
Name of the Device (s):	Oscilla A30, Oscilla A50, Oscilla A60
Product family (DMR):	ATM4
Classification:	Ila
Intended Use:	Diagnostic audiometric testing.
Part numbers:	See Appendix A in Id-0243 EC Declaration of Conformity
Notified Body name:	MDC medical device certification GmbH
Notified Body Address:	Kriegerstraße 6 70191 Stuttgart, Deutschland
Notified Body Identification number:	0483

Oscilla A/S declare that the products have been tested in accordance with the manufacturer's instructions, packaged, the manufacturer's user instructions included and compiled in accordance with the specifications of internal monitoring, verification and validation.

Oscilla A/S declares that the 3rd party medical equipment that is combined and used in the final product is CE marked and is used as intended from the 3rd party's legal manufacture.

For further product details refer to: Id-0243 EC Declaration of Conformity

Signature:

Joachim Boll, CEO & Partner

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

Aarhus, Denmark
15.11.2024



**ÅBOGADE 15, 8200 AARHUS
DENMARK**

Appendix A:

System packages

UDI-DI	Part/Ref no.	Description
05745000311002	1230	Oscilla® A30 w. DD65 headset, AudioConsole® and carrying bag
05745000311040	1231	Oscilla® A30 w. H210A headset, AudioConsole® and carrying bag
05745000311019	1232	Oscilla® A50 w. DD65 headset B71, AudioConsole® and carrying bag
05745000311057	1233	Oscilla® A50 w. DD65 headset and BC-2, AudioConsole® and carrying bag
05745000311064	1234	Oscilla® A50 w. H210A headset and B71, AudioConsole® and carrying bag
05745000311071	1235	Oscilla® A50 w. H210A headset and BC-2, AudioConsole® and carrying bag
05745000311118	1240	Oscilla® A50 w. DD65 headset and B81, AudioConsole® and carrying bag
05745000311125	1241	Oscilla® A50 w. H210A headset and B81, AudioConsole® and carrying bag
05745000311026	1236	Oscilla® A60 w. DD65 headset and B71, AudioConsole® and carrying bag
05745000311088	1237	Oscilla® A60 w. DD65 headset and BC-2, AudioConsole® and carrying bag
05745000311095	1238	Oscilla® A60 w. H210A headset and B71, AudioConsole® and carrying bag
05745000311101	1239	Oscilla® A60 w. H210A headset and BC-2, AudioConsole® and carrying bag
05745000311132	1242	Oscilla® A60 w. DD65 headset and B81, AudioConsole® and carrying bag
05745000311149	1243	Oscilla® A60 w. H210A headset and B81, AudioConsole® and carrying bag