EU Quality Management System Certificate

mdc medical device certification GmbH

Kriegerstr. 6, 70191 Stuttgart, Germany
Notified body (identification number 0483)

hereby certifies that the company

Oscilla A/S

Aabogade 15
8200 Aarhus
Denmark

has implemented and applies a quality management system in accordance with Annex IX, Chapter I of Regulation (EU) 2017/745 for conformity assessment of the devices listed on the following pages.

An audit by mdc has proven that this quality management system fulfils the following requirements:

Annex IX - Chapter I (Quality Management System)

of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

Surveillance is carried out in accordance with Annex IX, Section 3 of Regulation (EU) 2017/745.

This certificate consists of 2 pages. Details of the devices affected by this certificate as well as further information and conditions are included on the following pages.

Valid from:	2022-03-10	Registration No.	D1492000001
Valid until:	2027-03-09	Evaluation Report No.	209184

Stuttgart, 2022-03-10

Head of Notified Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-098

Devices:

Product: Oscilla Audiometer / A30, A50, A60

Risk class: IIa – not implantable
Basic-UDI-DI: 5745000311ATM4TW

Product: Oscilla AudioConsole PC-software

Risk class: IIa - not implantable
Basic-UDI-DI: 5745000311SW01VH
