CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Oticon Medical AB

(DUNS # 55-456-3994)

Main Site: Datavägen 37B

SE-436 32 Askim, Sweden

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

Brazil: Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

The management system is applicable to:

Design, manufacturing of hearing health care solutions, including sterile surgical implants, sound processors and accessories for fitting and use of the products.

Certificate Number:
0085299

Initial Certification Date:
2018-12-19

Certification Effective Date:
2018-12-19

Certification Expiry Date:
2021-12-18

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Calin Moldovean
President, Business Assurance

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