



DNV

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
C627603

Initial certification date:
2017-12-15

Expiry Date:
2026-12-14

This is to certify that the management system of

Atos Medical AB

Kraftgatan 8, SE-242 35, Hörby, Sweden

F006983

has been found to conform to the Quality Management System standard:

ISO 13485:2016 and the requirements of the following regulatory authorities

Australia:

- Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil:

- RDC ANVISA n. 665/2022
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009

Canada:

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

Japan:

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

United States:

- 21 CFR 803
- 21 CFR 806
- 21 CFR 807 – Subparts A to D
- 21 CFR 820

This certificate is valid for the following scope:

Design, development, manufacture and distribution of voice restoration systems including instruments for insertion, pulmonary rehabilitation systems including attachments, covers and accessories, jaw motion and swallowing rehabilitation systems, electrolarynx and tympanostomy tubes.

Place
Høvik

Effective Date:
2026-03-13



DNV Product Assurance AS is an MDSAP
Recognized Auditing Organization

For the issuing office:

DNV Product Assurance AS
Veritasveien 1, 1363 Høvik, Norway

Hazem Tinawi

Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

ACCREDITED UNIT: DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

Your certificate is stored in DNV's secure certificate storage, providing traceability and trust to further enhance the value of your certification. Anyone can easily verify the validity of a certificate and details through the QR code on the certificate or in the link, <https://certificatechecker.dnv.com/>, with the certificate number/manufacturer name.