



# MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:  
C627603

Initial certification date:  
2017-12-15

Expiration:  
2026-12-14

This is to certify that the management system of

## Atos Medical AB

Kraftgatan 8, 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:  
2023-12-15



DNV is an MDSAP authorised  
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](http://www.dnv.com)

All our Certificates are in blockchain system and as a first step you can validate the certificate details by scanning the QR code on the Certificate or in the link, <https://certificatechecker.dnv.com/> with the certificate number/manufacture name.