

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Atos Medical AB  
Kraftgatan 8  
SE-242 35 Hörby  
Sweden

Holds Certificate Number:

**MD 723330**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, development, manufacturing, 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.

Transfer from Intertek  
Certificate number: 13196-05

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-08-24

Latest Revision Date: 2022-02-12

Effective Date: 2020-12-15

Expiry Date: 2023-12-14

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