

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 rehabilitation systems and tympanostomy tubes.

Transfer from Intertek
Certificate number: 13196-05

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-08-24

Latest Revision Date: 2020-11-27

Effective Date: 2020-12-15

Expiry Date: 2023-12-14

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