

EC CERTIFICATION

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Organization:

ATOS Medical AB

Main Site: Kraftgatan 8, SE-242 35 Hörby, Sweden

Product Category:

- Laryngology and respiratory products
- Products for treatment of hearing disorders and infections in the ear

For further identification of the products covered, see the MDD product list/product schedule.

Certificate Number:

41310296-04

Initial Certification Date:

26 November 1996

Certificate Valid from:

16 October 2020

Certificate Expiry Date:

26 May 2024



Accred. no. 1003
Certification of
Management
Systems
ISO/IEC 17021-1

Peter Nermander

Certification Authority MDD

Intertek Semko AB, Kista, Sweden

16 October 2020

Signed Date

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The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.

