intertek
Total Quality. Assured.

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:

Aurena Laboratories AB

Main Site: Fjärrviksvägen 22, SE-653 50 Karlstad, Sweden

Product Category:

- Water based solution for endoscopic polypectomy
- Saline solution, for flushing and cleaning of eye, ear and wounds
- Saline solution, for flushing, cleaning and moisturizing of the nose, mouth and throat
- Saline solution for use with nebulizer
- Water based gel solution as Burn gel
- Petrolatum solution as an emollient and protective barrier
- Silicone based solutions as Adhesive remover and Barrier Film

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

Certificate Number:
41313991-04

Initial Certification Date:
16 May 2002

Certificate Valid from:
09 April 2021

Certificate Expiry Date:
26 May 2024

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

Peter Nermander
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

09 April 2021
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.