EC Certificate

FULL QUALITY ASSURANCE SYSTEM
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Certificate Number
41313991-01

Initial Certification Date
May 16, 2002

Certificate Valid from
May 17, 2017

Certificate Expiry Date
May 16, 2022

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.

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SWEDAC ACKREDITERING

Ackred. nr 1003
ISO/IEC 17021

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

Fjärrviksvägen 22, SE-653 50 Karlstad, Sweden

Product Category:

- Sterile solution for contact lenses
- Saline solution, as moisturizing nasal spray and flushing for cleaning of eye, ear and wound
- Flushing solutions for cleaning wounds
- Barrier spray for protection of uninjured skin
- Barrier Film
- Adhesive remover
- Throat Spray for irrigation and rinsing of mouth and throat
- Nebulizer saline Solution

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

May 12, 2017
Signed date

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