

# EC Certificate

## FULL QUALITY ASSURANCE SYSTEM

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

**Certificate Number**  
41313991-02

**Initial Certification Date**  
May 16, 2002

**Certificate Valid from**  
November 23, 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.*

*Intertek Semko AB  
Box 1103, SE-164 22 Kista,  
Sweden  
Telephone +46 8 750 00 00  
medtechsweden@intertek.com*



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:

- 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.

November 23, 2017

Signed date

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