



EC Declaration of Conformity

We: Aurena Laboratories AB
Fjärrviksvägen 22
653 50 Karlstad
Sweden

Certify that: Versions of Aurena Eye and Wound Wash, with reference number:
1002-1
1002-2
1002-3

With intended use: Sterile isotonic saline solution for rinsing/cleansing of eye and wounds

Is in conformity with the applicable provisions of: Council Directive 93/42/EEC concerning medical devices via the Swedish implementation LVFS 2003:11, annex II with amendments (with the exemption of section 4).

Device classification according to 93/42/EEC: Class IIa

EC Certificate Number: 41313991-01

Notified Body MDD: Intertek Semko AB (Identification no. 0413)

For Aurena Laboratories AB:


Anders Bared
Director
Regulatory affairs



Dated: 2017-08-23