EC Certificate

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

Certificate Number
41315275-04

Initial Certification Date
November 17, 2005

Certificate Valid from
February 15, 2017

Certificate Expiry Date
December 10, 2018

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:

Orkla Care AB

Visit address: Svetsarvägen 15, Solna, Sweden
Postal address: Box 1336, SE 171 26 Solna, Sweden

Product Category:

- Quick Healing plasters
- Hydrocolloid Dressings
- Wound care products
- Dressings
- Adhesive bandages
- Wet wipes
- Ingested gastric satiety device
- Burn Gel
- Bandages
- Eye/Wound Wash

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

February 15, 2017
Signed date

Bob Andersson, Certification Authority MDD
Intertek Semko AB, Kista, Sweden

2015-09-30