

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.

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:

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



DECLARATION OF CONFORMITY PROCEDURE PACK

This is a declaration made in accordance with the requirements in Article 12 of the Medical device directive 93/42/EEC including amendments to date as implemented in Swedish law.

Procedure Pack:

REF: 390101 **CEDERROTH FIRST AID KIT MEDIUM**

Contents as stated on next page

Manufacturer:

Orkla Care AB Svetsarvägen 15

Box 1336

SE-171 26 Solna

Sweden

The manufacturer or the procedure pack has evidence that the conformity assessment procedures have been applied to each medical device in the package; and that each medical device in the package complies with the applicable provisions of the essential requirements.

Each medical device in the system or procedure pack is intended to be used for its original intended purpose. The components are intended to be used as separate items and therefore there is no need for mutual compatibility of each medical device or other component in the package.

Neither the original packaging nor the instructions for use for the separate items are changed.

The processes of manufacturing and packaging of the procedure pack have been subjected to documented methods of internal control and inspection that ensures the safety, quality, performance and effectiveness of each item in the package.

2016-02-23

Teija Ålander

Quality Assurance and Regulatory Affairs Manager

Wound Care Division, Orkla Care AB

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International

VAT No: www.orkia.se

www.salvequick.com www.firstaid.cederroth.com



REF 390101 CEDERROTH FIRST AID KIT MEDIUM

Contents		
Product	Medical device class	CE NB #
First Aid Instruction	NA	NA
Cederroth Breathing Mask	I	CE
Gloves	I	CE
Cederroth Safety Hand Cleanser	NA (Cosmetic)	NA
Cederroth Emergency Blanket	I	CE
Scissors	NA	NA
Cederroth 4-in-1 Bloodstopper	I sterile	CE0413
Cederroth 4-in-1 Mini Bloodstopper	l sterile	CE0413
Cederroth Burn Gel dressing	lla	CE0413
Salvequick Plaster	I	CE
Salvequick Wound Cleanser	l sterile	CE0413
Salvequick Maxi Cover	I sterile	CE0413
Cederroth Elastic bandage	ı	CE