

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: 51011008 CEDERROTH FIRST AID & BURN STATION SET DIN 13157

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.

2020-06-16

Teija Ålander
Sr Quality Assurance and Regulatory Affairs Manager
Wound Care, Orkla Care AB

REF 51011008

CEDERROTH FIRST AID & BURN STATION SET DIN 13157

| Contents | | |
|---|----------------------|---------|
| Product | Medical device class | CE NB # |
| REF 51011003: | | |
| Cederroth 4-in-1 Bloodstopper | I sterile | CE0413 |
| Cederroth 4-in-1 Mini Bloodstopper | I sterile | CE0413 |
| Burn Dressing 2-p | Ila | CE0413 |
| Burn Gel Spray | Ila | CE0413 |
| Salvequick Blue Detectable, regular + regular/fingertip | I sterile | CE0413 |
| Cederroth Soft Foam Bandage, Blue | I | CE |
| Salvequick Wound Cleanser 20-p | Ila | CE0413 |
| Cederroth Breathing Mask | I | CE |
| First Aid Instruction (label) | NA | NA |
| Key to the dispensers | NA | NA |
| REF 51611220: | | |
| First Aid Instruction DIN | NA | NA |
| Gloves | I | CE |
| Cederroth Emergency Blanket | I | CE |
| Cederroth 4-in-1 Bloodstopper | I sterile | CE0413 |
| Cederroth 4-in-1 Mini Bloodstopper | I sterile | CE0413 |
| Salvequick Surgical tape | I | CE |
| Cederroth Triangular bandage | I | CE |
| Salvequick Instant Cold Pack | Ila | CE0120 |
| Elastic bandage 8cm x 4m | I | CE |
| Elastic bandage 6cm x 4m | I | CE |
| Eye compress | I sterile | CE0197 |
| Wound compress | I Sterile | CE0197 |
| Dressing 60 x 80 cm | I sterile | CE0197 |
| Salvequick Mixed plasters | I | CE |
| Scissors | NA | NA |
| Plastic bag | NA | NA |
| Wall Bracket | NA | NA |

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