# 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: 51011013 CEDERROTH FIRST AID BURN KIT**
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.

2020-03-31

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

**REF 51011013**
**CEDERROTH FIRST AID KIT MEDIUM**

| **Contents** | | |
|---|---|---|
| **Product** | **Medical device class** | **CE NB #** |
| Cederroth Burn Gel Face Mask 30x40 cm | IIb | CE0197 |
| Cederroth Burn Gel Dressing 20x20 cm | IIb | CE0197 |
| Cederroth Burn Gel Dressing 10x10 cm | IIa | CE0413 |
| Cederroth Burn Gel 100 ml | IIa | CE0413 |
| Cederroth Fixing Net | I | CE |
| Cederroth Elastic Fixing Bandage | I | CE |
| Cederroth 4-in-1 | I s | CE0413 |
| Scissors | I | CE |
| Gloves | I | CE |
| First Aid Instruction | N/A | N/A |
| List of contents | N/A | N/A |
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