

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.

2019-05-27

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



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	I sterile	CE0413
Cederroth Burn Gel dressing	lla	CE0413
Salvequick Plaster	I	CE
Salvequick Wound Cleanser	I sterile	CE0413
Salvequick Maxi Cover	I	CE
Cederroth Elastic bandage	I	CE