

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.

Manufacturer: Orkla Care AB
Svetsarvägen 15
Box 1336
SE-171 26 Solna
Sweden

Procedure Pack: REF: 51011007 CEDEROTH FIRST AID KIT LARGE DIN 13157

Contents: See attachment

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 principles.

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 process of manufacturing the procedure pack, and verification and packaging of the procedure pack has been subjected to a documented method of internal control and inspection that ensures the safety, quality, performance and effectiveness of each item in the package.

2018-08-24



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

REF 51011007

CEDERROTH FIRST AID KIT LARGE DIN 13157

Products in procedure pack		
Product	Medical device class	CE NB #
First Aid instruction	NA	NA
Gloves	I	CE
Emergency blanket	I	CE
Scissors	NA	NA
Cederroth 4-in-1	I sterile	CE 0413
Cederroth 4-in-1 mini	I sterile	CE 0413
Salvequick Surgical tape	I	CE
Cederroth Elastic bandage 8cm x 4m	I	CE
Salvequick Instant Cold pack	Ila	CE 0120
First Aid Instruction DIN	NA	NA
Dressing 10 x 10 cm	I sterile	CE0197
Dressing cloth 60 x 80 cm	I sterile	CE0197
Dressing cloth 20 x 30 cm	I	CE
Elastic bandage 6cm x 4m	I sterile	CE0197
Eye compress	I sterile	CE0197
Salvequick Mixed plasters	I	CE
Plastic bag	NA	NA