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: 51011006 CEDERROTH WOUND CARE DISPENSER**

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.

2018-12-03

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

REF 51011006
CEDERROTH WOUND CARE DISPENSER

Products in procedure pack		
Product	**Medical device class**	**CE NB #**
Salvequick Wound Cleanser 40-p	IIa	CE 0413
Cederroth Soft Foam Bandage 4,5m	I	CE
Salvequick Plastic plasters	I	CE
Salvequick Textile plasters	I	CE
Salvequick Textile XL plasters	I	CE
Key to dispenser	NA	NA

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