

STATEMENT PROCEDURE PACKS

REGULATION ON MEDICAL DEVICES (EU) 2017/745, ARTICLE 22

ORKLA WOUND CARE AB

SRN: SE-PR-000021131

This statement is issued by Orkla Wound Care AB in accordance with Article 22 of the Regulation on Medical Devices (EU) 2017/745.

Orkla Wound Care AB has combined devices bearing a CE marking with other devices or products according to paragraph 1 of Article 22 of the Regulation on Medical Devices (EU) 2017/745, in a manner that is compatible with the intended purpose of the devices or other products and within the limits of use specified by their manufacturers, in order to place them on the market as a procedure pack.

Orkla Wound Care AB hereby declares that:

- we have verified the mutual compatibility of the devices and, if applicable other products, in accordance with the manufacturers' instructions and have carried out the activities in accordance with those instructions,
- we have packaged the procedure packs and supplied relevant information to users incorporating the information to be supplied by the manufacturers of the devices or other products which have been put together,
- the activity of combining devices and, if applicable, other products as a procedure pack was subject to appropriate methods of internal monitoring, verification and validation.

Basic UDI-DI: 7310610502004D

EMDN (CND) code: V0501

GMDN code: 44047

Medical purpose: Assortments of products to be used in First Aid situations.
Not intended for refill.

List of procedure packs on following page(s).

REF	Name of Procedure Pack		Highest risk class
2596	Cederroth First Aid	Protection Kit	MDR, Class I
1893	Cederroth First Aid	Net Dressing	MDD, Class I s
1880	Cederroth First Aid/ Salvequick	Wound Cleansers & Plasters	MDD, Class IIa
2030	Cederroth First Aid	First Aid Refill for large F/A cabinet	MDD, Class I s
264000	Cederroth First Aid	Refill First Aid Panel	MDD, Class IIa
51011002			
New REF: 51011039	Cederroth First Aid	Refill to Cederroth First Aid station	MDD, Class IIa
51000026	Cederroth First Aid	Set of mixed DIN products	MDD, Class I s
51011038	Cederroth First Aid	Refill to Cederroth Wound Care dispenser	MDD, Class IIa

Solna 2022-05-02



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Person Responsible for Regulatory Compliance
Orkla Wound Care AB