

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: 73106105010048

EMDN (CND) code: V0501

GMDN code: 43000

Medical purpose: Assortments of products to be used in First Aid situations, packed in mobile kits, dispensers or first aid stations.

List of procedure packs on following page(s).

REF	Name of Procedure Pack		Highest risk class
Dispensers			
490700	Cederroth First Aid/ Salvequick	Plaster Dispenser	MDR, Class I
490704	Cederroth First Aid/ Salvequick	Plaster Dispenser Customer branded	MDR, Class I
51000024	Cederroth First Aid/ Salvequick	Plaster Dispenser Customer branded	MDR, Class I
51030130	Cederroth First Aid/ Salvequick	Plaster Dispenser Blue Detectable	MDR, Class I
51011024	Cederroth First Aid	Soft Foam Bandage Dispenser	MDR, Class I
490754	Cederroth First Aid/ Salvequick	Plaster Dispenser CAP Blue Customer branded	MDD, Class I s
51011006	Cederroth First Aid	Wound Care Dispenser	MDD, Class IIa
51011009	Cederroth First Aid	Wound Care Dispenser BLUE	MDD, Class IIa
First Aid Stations			
191400	Cederroth First Aid	First Aid Panel Small	MDD, Class I s
291400	Cederroth First Aid	First Aid Cabinet Small	MDD, Class I s
290900	Cederroth First Aid	First Aid Cabinet Double Door	MDD, Class IIa
490920 New REF: 51011026	Cederroth First Aid	First Aid Station	MDD, Class IIa
490922 New REF: 51011033	Cederroth First Aid	First Aid Station Customer branded	MDD, Class IIa
490927 New REF: 51011031	Cederroth First Aid	First Aid Station Customer branded	MDD, Class IIa
490928 New REF: 51011034	Cederroth First Aid	First Aid Station Customer branded	MDD, Class IIa
490929 New REF: 51011027	Cederroth First Aid	First Aid Station Customer branded	MDD, Class IIa
490930 New REF: 51011030	Cederroth First Aid	First Aid Station Customer branded	MDD, Class IIa
490931 New REF: 51011028	Cederroth First Aid	First Aid Station Customer branded	MDD, Class IIa

REF	Name of Procedure Pack		Highest risk class
490934 New REF: 51011029	Cederroth First Aid	First Aid Station Customer branded	MDD, Class IIa
51011003	Cederroth First Aid	First Aid & Burn Station	MDD, Class IIa
51011004	Cederroth First Aid	First Aid & Burn Station Customer branded	MDD, Class IIa
Set with station and mobile First Aid kit			
51011000 New REF: 51011032	Cederroth First Aid	First Aid Station set DIN 3157	MDD, Class IIa
51011008	Cederroth First Aid	First Aid & Burn Station Set DIN13157	MDD, Class IIa
Mobile First Aid kits			
390100	Cederroth First Aid	First Aid Kit small	MDD, Class IIa
390101	Cederroth First Aid	First Aid Kit medium	MDD, Class IIa
390102	Cederroth First Aid	First Aid Kit large	MDD, Class IIa
390103	Cederroth First Aid	First Aid Kit X-Large	MDD, Class IIa
390104	Cederroth First Aid	First Aid Kit DIN	MDD, Class IIa
51611220	Cederroth First Aid	First Aid Kit DIN 13157 (Sold only as part of 51011000)	MDD, Class IIa
51011007	Cederroth First Aid	First Aid Kit Large DIN	MDD, Class IIa
51011013	Cederroth First Aid	First Aid Burn Kit	MDD, Class IIb
Eye Wash			
721500	Cederroth First Aid	Eye Wash station	MDD, Class I s
51011042	Cederroth First Aid	Eye Wash 5x500 ml in Case	MDD, Class I s

Solna 2022-05-02



Teija Ålander
Regulatory Affairs and Quality Manager
Person Responsible for Regulatory Compliance
Orkla Wound Care AB