

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	Class I
490704	Cederroth First Aid/ Salvequick	Plaster Dispenser Customer branded	Class I
51000024	Cederroth First Aid/ Salvequick	Plaster Dispenser Customer branded	Class I
51030130	Cederroth First Aid/ Salvequick	Plaster Dispenser Blue Detectable	Class I
51011024	Cederroth First Aid	Soft Foam Bandage Dispenser	Class I
51011006	Cederroth First Aid	Wound Care Dispenser	Class IIa
51011009	Cederroth First Aid	Wound Care Dispenser BLUE	Class IIa
First Aid Stations			
191400	Cederroth First Aid	First Aid Panel Small	Class I s
291400	Cederroth First Aid	First Aid Cabinet Small	Class I s
290900	Cederroth First Aid	First Aid Cabinet Double Door	Class IIa
51011026	Cederroth First Aid	First Aid Station	Class IIa
51011027	Cederroth First Aid	First Aid Station Customer branded	Class IIa
51011028	Cederroth First Aid	First Aid Station Customer branded	Class IIa
51011029	Cederroth First Aid	First Aid Station Customer branded	Class IIa
51011030	Cederroth First Aid	First Aid Station Customer branded	Class IIa
51011031	Cederroth First Aid	First Aid Station Customer branded	Class IIa
51011033	Cederroth First Aid	First Aid Station Customer branded	Class IIa
51011003	Cederroth First Aid	First Aid & Burn Station	Class IIa
51011004	Cederroth First Aid	First Aid & Burn Station Customer branded	Class IIa
Set with station and mobile First Aid kit			
51011032	Cederroth First Aid	First Aid Station set DIN 3157	Class IIa
51011008	Cederroth First Aid	First Aid & Burn Station Set DIN13157	Class IIa
Mobile First Aid kits			
390100	Cederroth First Aid	First Aid Kit small	Class IIa
390101	Cederroth First Aid	First Aid Kit medium	Class IIa
390102	Cederroth First Aid	First Aid Kit large	Class IIa

REF	Name of Procedure Pack		Highest risk class
390103	Cederroth First Aid	First Aid Kit X-Large	Class IIa
390104	Cederroth First Aid	First Aid Kit DIN	Class IIa
51611220	Cederroth First Aid	First Aid Kit DIN 13157 (Sold only as part of 51011000)	Class IIa
51011007	Cederroth First Aid	First Aid Kit Large DIN	Class IIa
51011013	Cederroth First Aid	First Aid Burn Kit	Class IIb
Eye Wash			
721500	Cederroth First Aid	Eye Wash station	Class I s

Solna 2023-12-14

Johanna Brinck
[Johanna Brinck \(Dec 14, 2023 15:04 GMT+1\)](#)

Johanna Brinck
 Head of Regulatory Affairs and Quality
 Person Responsible for Regulatory Compliance
 Orkla Wound Care AB

Statement Procedure packs_Reusable_Orkla Wound Care AB_EN_V10

Final Audit Report

2023-12-14

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