

EU DECLARATION OF CONFORMITY

REGULATION ON MEDICAL DEVICES (EU) 2017/745, ANNEX IV

ORKLA WOUND CARE AB

SRN: SE-MF-000021041

This EU Declaration of Conformity is issued under the sole responsibility of Orkla Wound Care AB.

We hereby declare that the Medical Device products listed below conform to the Regulation on Medical Devices (EU) 2017/745.

Conformity assessment route:

The products are class IIa medical devices and have been CE marked in accordance with Annex IX of MDR 2017/745.

Verified by Notified Body, Intertek Medical Notified body # 2862, certificate #: 28620123341.

Basic UDI-DI: 7340210118004H

EMDN (CND) code: M04040501

GMDN code: 47693

Intended purpose: The product is intended to be used as first aid treatment for cooling and covering of minor burns, scalds and sunburns.

REF	Name of product	Risk class
901900	Cederroth Burn Gel Dressing 10cm x 10cm	IIa
51011014	Cederroth Burn Gel Dressing/Face Mask 30cm x 40cm	IIa
51011015	Cederroth Burn Gel Dressing 20cm x 20cm	IIa

Common Specifications applied: No applicable CS available.

Solna 2024-10-02

Johanna Brinck
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Johanna Brinck
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