

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.

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: 7340210120003G

EMDN (CND) code: M04040501 **GMDN code:** 47694

Intended purpose: The product is to be used as a first aid for minor burns, scalds, sunburns

and radiation injured skin.

Risk class REF Name of product

51011005 Cederroth Burn Gel 100 ml lla

Common Specifications applied:

No CS available

Solna 2023-12-18

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

www.cederroth.com

DoC Cederroth Burn Gel 100 ml_MDR_EN

Final Audit Report 2023-12-18

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By: Teija Ålander (teija.alander@orkla.se)

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