

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 Is medical devices and have been CE marked in accordance with Annex IX, Chapters I and III of MDR 2017/745.

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

Basic UDI-DI: 73402101010037

EMDN (CND) code: M03040101

GMDN code: 47011

Intended purpose: The products are intended to be used in first aid situations as a mechanical barrier, for absorption of exudates or for support. The products have four functions:

1. Pressure pad for heavy bleeding
2. Protective dressing for superficial wounds
3. Burn dressing with special wound protecting surface
4. Temporary support dressing

Because of the four functions the products replace a variety of traditional first aid dressings and compresses.

The small bloodstopper is especially suitable for fingers and toes.

REF	Name of product	Risk class
1910	Cederroth 4-in-1	Is
1911	Cederroth 4-in-1 mini	Is

Common Specifications applied: No CS available

Solna 2024-02-19



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Person Responsible for Regulatory Compliance

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DoC Cederroth 4-in-1 Bloodstoppers_MDR_EN

Final Audit Report

2024-02-19

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