

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 I medical devices and have been CE marked in accordance with MDR 2017/745 Article 52 (7); Conformity assessment procedure of class I medical devices.

Basic UDI-DI: 73402101150042

EMDN code: M03030102

GMDN code: 58964

Intended purpose: The products are intended to be used as a mechanical barrier and for absorption of exudates from minor wounds or as a pressure bandage. The products may also be used for fixation of dressings.

REF	Name of product		Risk class
666150	Cederroth First Aid	Soft Foam Bandage Blue 40cm	I
51011010	Cederroth First Aid	Soft Foam Bandage Blue 6cm x 4,5m	I
51011011	Cederroth First Aid	Soft Foam Bandage Blue 6cm x 2m	I
51011018	Cederroth First Aid	Soft Foam Bandage Beige 3cm x 4,5m	I
51011019	Cederroth First Aid	Soft Foam Bandage Beige 6cm x 2m	I
51011020	Cederroth First Aid	Soft Foam Bandage Beige 6cm x 4,5m	I
51011021	Cederroth First Aid	Soft Foam Bandage Black 6cm x 4,5m	I
51011022	Cederroth First Aid	Soft Foam Bandage Blue 3cm x 4,5m	I
51011023	Cederroth First Aid	Soft Foam Bandage Blue 40cm	I

Common Specifications applied: No applicable CS available

Solna 2024-08-06

Johanna Brinck


Johanna Brinck (Aug 6, 2024 18:42 GMT+2)

Head of Regulatory and Quality

Person Responsible for Regulatory Compliance

Orkla Wound Care AB

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