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:	73402100580052		
EMDN (CND) code:	M040405	**GMDN code:**	47764
Intended purpose:	The product is intended to be used on minor burns, scalds or wounds for protection and to cool and soothe. The device provides a moist wound environment which is beneficial for healing.		

REF	**Name of product**	**Risk class**
901903	Cederroth Burn Cover	IIa, Rule 4

Common Specifications applied:
No CS available

Solna 2024-04-25

Johanna Brinck

Johanna Brinck (Apr 25, 2024 10:30 GMT+2)

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

DoC Cederroth Burn Cover_MDR_EN

Final Audit Report 2024-04-25

Created:	2024-04-25
By:	Teija Ålander (teija.alander@orkla.se)
Status:	Signed
Transaction ID:	CBJCHBCAABAAoIaxkBNTJ6TFjCGnebSJUUYvR9sw7iUT

"DoC Cederroth Burn Cover_MDR_EN" History

Document created by Teija Ålander (teija.alander@orkla.se)
2024-04-25 - 7:39:05 AM GMT

Document emailed to Johanna Brinck (johanna.brinck@orkla.se) for signature
2024-04-25 - 7:39:29 AM GMT

Email viewed by Johanna Brinck (johanna.brinck@orkla.se)
2024-04-25 - 8:27:03 AM GMT

Document e-signed by Johanna Brinck (johanna.brinck@orkla.se)
Signature Date: 2024-04-25 - 8:30:06 AM GMT - Time Source: server

Agreement completed.
2024-04-25 - 8:30:06 AM GMT