



EU Declaration of Conformity according to MDR

Title: Epaderm Cream

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden, SRN SE-MF-000014042, being exclusively responsible manufacturer for conformity of the device/s; declare that the devices listed in the attached schedule are in conformity with the provisions of the Medical Device Regulation 2017/745, concerning medical devices.

Other Union Legislation applicable: Not applicable

Trade name / Product name:	Epaderm Cream
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Product Classification: MDR Class IIa

MDR Classification Rule: 4, 21

Sterility: Non-sterile

Measuring Function: No

This declaration is supported by a conformity assessment procedure in accordance with Annex/es: IX
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Common Specification: No CS is applicable

Certificate number:	MDR 722028
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Issued by:	BSi
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Id No: 2797

(Notified Body Name)

NB. For non-sterile, non-measuring Class I products, no certificate is issued by a Notified Body.

Mölnlycke Health Care AB issues this declaration in recognition of applied harmonized standards.

Signed for and on behalf of Mölnlycke Health Care AB

Place of Issue: Göteborg, Sweden

Date: 2023-12-05

Function:

Regulatory Affairs Excellence Manager

Name: Karin Darle Olsson

Signature:

Title: Epaderm Cream

Generic product information	
Intended Purpose:	For the management of dry skin conditions, eczema and psoriasis
Basic UDI-DI:	733243000000000042JQ
GMDN Code:	46206 Skin moisture barrier dressing
EMDN Code:	M9002 PROTECTIVE DEVICES, LUBRICANTS AND SOOTHING DEVICES (SPRAYS, GELS, FLUIDS AND CREAMS)

Product References Covered by this Declaration:	Product	Product Descriptor:
99400820	Epaderm Cream 500g x 6	2 in 1 Emollient and Skin Cleanser
99400821	Epaderm Cream 50g x 12	2 in 1 Emollient and Skin Cleanser
99400822	Epaderm Cream 25g x 12	2 in 1 emollient and skin cleanser
99400823	Epaderm Creme 50g x 12 Benelux	2 in 1 Emollient and skin cleanser
99400824	Epaderm Creme 500g x 6 Benelux	2 in 1 Emollient and skin cleanser
99400825	Epaderm Cream 150g x 12	2 in 1 Emollient and Skin Cleanser
99400837	Epaderm Cream 50g x 12 Iberia	2 in 1 emollient and skin cleanser
99400838	Epaderm Cream 500g x 6 Iberia	2 in 1 emollient and skin cleanser
99400850	Epaderm Cream 500g Pump x 6 ANZ	2 in 1 Emollient and Skin Cleanser
99400851	Epaderm Cream 50g Pump x 12 ANZ	2 in 1 Emollient and Skin Cleanser
99400860	Epaderm Cream Junior 50g x 12	2 in 1 Emollient and skin cleanser
99400861	Epaderm Cream Junior 150g x 12	2 in 1 Emollient and skin cleanser