



EU Declaration of Conformity according to MDR

Title: Epaderm Ointment

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 Ointment
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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: 2024-06-26

Function: Global Regulatory Affairs Director

Name: Christina Lewing

Signature:



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Generic product information	
Intended Purpose:	For the management of eczema, psoriasis and other dry skin conditions
Basic UDI-DI:	733243000000000373KJ
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:
400861	Epaderm Ointment 25g	Epaderm product
99400816	Epaderm Ointment 125g	Epaderm product
99400817	Epaderm Ointment 500g	Epaderm product
99400818	Epaderm Ointment 1kg	Epaderm product
99400846	Epaderm Ointment ANZ 125g	Epaderm product
99400847	Epaderm Ointment ANZ 500g	Epaderm product
99400871	Epaderm Ointment Junior 125g	Epaderm Product