

EC DECLARATION OF CONFORMITY

Legal Manufacturer Thornton and Ross Ltd
Linthwaite
Huddersfield
HD7 5QH, UK

EU Authorised Representative HÄLSA Pharma GmbH
Maria-Goeppert-Straße 5
D-23562 Lübeck
Germany

We herewith declare under our sole responsibility that our products as listed below are in conformity with the provisions of the EC Directive 93/42/EEC as amended by 2007/47/EC, which apply to them. The appropriate registrations have been made to the Medicines and Healthcare products Regulatory Agency (MHRA), as the Competent Authority in the United Kingdom.

Product Name:

Hedrin® Protect & Go
Hedrin® Protect & Go (Fragrance Free)

GMDN:

46982 - Lice treatment solution, synthetic

Description:

A white opaque aqueous gel containing Purified Water, PEG 6 Caprylic Capric Glycerides, PEG 12 Dimethicone, Octane 1,2-diol, Orange & Mango Fragrance (fragranced version only), Carbomer (Carbopol Ultrez), Sodium Hydroxide.

Thornton and Ross Ltd, agrees to develop, implement and maintain a post-production experience monitoring process, including the notification of reportable events under the European Medical Vigilance System Guidelines.

This declaration is based on Annex VII of the Medical Device Directive 93/42/EEC as amended by 2007/47/EC. The classification of the device is Class I.

Signed on the behalf of Thornton and Ross Ltd:

Name: Teresa Mellor
Title: Regulatory Affairs Manager

Signature Teresa Mellor Date 29/04/21

Electronically signed by:
Teresa Mellor
Date: Apr 29, 2021
07:20 GMT+1

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Final Audit Report

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