

## EC DECLARATION OF CONFORMITY

Legal Manufacturer: Thornton and Ross Ltd  
Linthwaite  
Huddersfield  
HD7 5QH

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<sup>®</sup> Once Spray Gel

**GMDN**

46982- Lice treatment solution, synthetic

**Description:**

Viscous turbid, colourless to off white liquid suspension containing: Dimeticone, 1,6,10-Dodecatrien-3-ol, 3,7,11-trimethyl, PEG/PPG Dimeticone Co-polymer, Silica Silylate;  
See the attached Appendix I for packs and sizes marketed.

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: Ashley Brierley

Title: Quality and Regulatory Director

Signature

*Ashley Brierley*

Date

*3/7/2013*

## Appendix I

### Hedrin® Once Spray Gel

Packaged in a HDPE Bottle with a trigger spray.

Sage Code	SAP Code	Product Name	SIZES
059005	155983	Hedrin® Once Spray Gel	60 ml e
059013	155561	Hedrin® Once Spray Gel	100 ml e

Packaged in a PET Bottle with a trigger spray.

Sage Code	SAP Code	Product Name	SIZES
059234	155565 (AT)	Hedrin® Turbo Spray Gel	60 ml e
059218	155559 (AU)	Hedrin® 15 Spray Gel	100 ml e
059307	164401 (BE)	Silikom Once Spray Gel	100ml e
059285	163664 (CEE)	Hedrin® Once Spray Gel	60ml e
059080	155566 (CY)	Hedrin® Fast Spray Gel	60 ml e
059188	155560 (CZ)	Hedrin® Once Spray Gel	100 ml e
059277	162120 (DE)	Hedrin® Once Spray Gel	60ml e
059315	163537 (ES)	Neositrin® Spray Gel	60 ml e
059323	163536 (ES)	Neositrin® Spray Gel	100 ml e
059021	155669 (FR)	Pouxit XF	100 ml e
059056	155562 (GR)	Hedrin® Plus Spray Gel	100 ml e
059048	155563 (IL)	Hedrin® Once Spray Gel	100 ml e
059145	160807 (IL)	Hedrin® Once Spray Gel	250ml e
059196	155567 (NOR)	Hedrin® Once Spray Gel	60 ml e
059161	155564 (NOR)	Hedrin® Once Spray Gel	100ml e
059293	163722 (PL)	Hedrin® Raz Żel w Sprayu	60 ml e
059269	161750 (RU)	Hedrin® Once Spray Gel	60ml e
059153	155571 (UA)	ХедРінг ЕКСТРА	60 ml e