

Declaration of Conformity

1. Manufacturer: Oystershell NV (SRN: BE-MF-000011797 and SRN BE-PR-000024807), Nijverheidsweg 10, 9820 Merelbeke, Belgium, declares this EU declaration of conformity is issued under his sole responsibility.

2. The product* with Basic UDI-DI: 5410765ElimaGreen5T

Device name	X92 number	Volume (mL/g)	Master Article	Risk class / Rule ¹
ELIMAX GREEN LOTION	X92001752	200 ml	62100023	Class I / Rule 1
ELIMAX GREEN LOTION	X92001752	100 ml	62100025	

3. Intended purpose of the device: *Treatment of head lice (pediculosis capitis) and nits*

4. Described above is in conformity with the Regulation:

Document No.	Title	Edition / Date of issue
EU MDR 2017/745	Medical Device Regulation	Current version, including EU MDR 2020/561, EU MDR 2023/502 and EU MDR 2023/607

5. Additional information (conformity procedure, Notified Body, CE certificate, etc.): Conformity assessment procedure for CE marking: EU MDR 2017/745, Article 52.7 and Annex II and Annex III.

Merelbeke, 05/06/2024.



Pepperstreet Capital BV*
 *Permanently represented by
 Bart Rossel
 CEO Oystershell NV



Liesbeth Hoste
 Head of Regulatory Affairs
 Oystershell NV

¹ See risk classification in Medical Device Regulation, Annex VIII.

***OTHER BRAND NAMES COVERED BY THIS DECLARATION OF CONFORMITY:**

STANDALONES:

Reference	Brand name	UDI-DI	Country	Volume (mL/g)	Master Article
02100306	STOP PIOLHOS LOÇÃO – ANTI LUIS LOTION	05410765005335	PT – NL	100 ml	62100025
02100311	PARASIDOSE LOTION VEGETALE	05410765005403	FR	200 ml	62100023
02100312	ANTI-BRUMM BY ELIMAX GREEN	05410765005410	CH	100 ml	62100025
02100314	HEDRIN ONCE NATURAL	05410765005465	DE	100 ml	62100025
02100315	HEDRIN ONCE NATURAL	05410765005434	DK/FI/NO/SE	100 ml	62100025
02100317	HEDRIN ONCE NATURAL	05410765005441	DK/FI/NO/SE	200 ml	62100023
02100318	HEDRIN ONCE NATURAL	05410765005472	IE	100 ml	62100025

PROCEDURE PACK: These article numbers are sold as a Procedure Pack according to Art. 22 of EU MDR 2017/745., including a Lotion and a comb. This DOC covers the standalone Lotion.

Reference	Brand name	UDI-DI	Country	Volume (mL/g)	Master Article
02100309	POUXIT FLASH VEGETAL LOZIONE	05410765005359	IT	100 ml	62100025
02100286	ELIMAX LOTION NATURELLE – NATUURLIJKE LOTION	05410765003706	BE	200 ml	62100023