

## Declaration of Conformity

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

2. The product X92001483 with Basic UDI-DI: 5410765ElimaxShampooCK

| Device name          | Package | Ref. number | Risk class / Rule <sup>1</sup> |
|----------------------|---------|-------------|--------------------------------|
| ELIMAX SHAMPOO 250ML | 250 ml  | 62060003    | Class I/Rule 1                 |
| ELIMAX SHAMPOO 200ML | 200 ml  | 62060018    | Class I/Rule 1                 |
| ELIMAX SHAMPOO 100ML | 100 ml  | 62060023    | Class I/Rule 1                 |

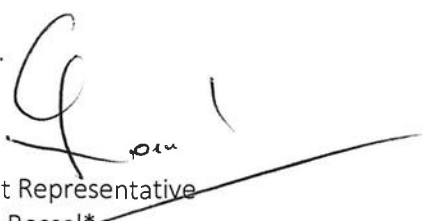
3. Intended purpose of the device: *Lice and nit treatment*

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         |

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, 09/08/2023.

  
 Management Representative  
 Bart Rossel\*  
 \*Representing Pepperstreet Capital BV  
 Oystershell NV

  
 Head of Regulatory Affairs  
 Liesbeth Hoste  
 Oystershell NV

<sup>1</sup> See risk classification in Medical Device Regulation, Annex VIII.

### OYSTERSHELL NV

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 www.oystershell.com

IBAN: BE23 3900 5661 2891  
 BIC: BBRUBEBB  
 IBAN: BE25 7330 0848 3082  
 BIC: KREDBEBB

\*Other brand names covered by this Declaration of Conformity:

| Reference | Device name                                        | UDI-DI (GTIN)  | Country | Package | Master Reference |
|-----------|----------------------------------------------------|----------------|---------|---------|------------------|
| 02060049  | LINICIN PLUS SHAMPOO 250ML DK                      | 05410765002426 | DK      | 250 ml  | 62060003         |
| 02060051  | ELIMAX SHAMPOO 250ML BE-FR                         | 05410765002440 | BE      | 250 ml  | 62060003         |
| 02060053  | ELIMAX SHAMPOO 250ML AT                            | 05410765004628 | AT      | 250 ml  | 62060003         |
| 02060078  | BEVITAMED TÄISHAMPOO 250ML                         | 05410765004635 | FI      | 250 ml  | 62060003         |
| 02060103  | LINICIN PLUSS SHAMPOO 250ML NO                     | 05410765004659 | NO      | 250 ml  | 62060003         |
| 02060126  | ANTI-BRUMM BY ELIMAX LAUS STOPP 2IN1 SHAMPOO 250ML | 05410765004666 | CH      | 250 ml  | 62060003         |
| 02060160  | PARASIDOSE SHAMPOING 2EN1 250ML                    | 05410765003850 | FR      | 250 ml  | 62060003         |
| 02060151  | PARASIDOSE SHAMPOING 2EN1 200ML                    | 05410765004680 | FR      | 200 ml  | 62060018         |
| 02060022  | BEVITAMED TÄISHAMPOO 100ML FI                      | 05410765004680 | FI      | 100 ml  | 62060023         |
| 02060031  | PRIODERM SHAMPOO PLUS 100ML                        | 05410765004697 | NL      | 100 ml  | 62060023         |
| 02060037  | LINICIN PLUS SHAMPOO 100ML DK                      | 05410765004710 | DK      | 100 ml  | 62060023         |

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|          |                                                       |                |                         |        |          |
|----------|-------------------------------------------------------|----------------|-------------------------|--------|----------|
| 02060038 | LINICIN PLUSS SHAMPOO 100ML NO                        | 05410765004727 | NO                      | 100 ml | 62060023 |
| 02060039 | AFTIR DUO SHAMPOO 100ML                               | 05410765004734 | IT                      | 100 ml | 62060023 |
| 02060048 | ELIMAX SHAMPOO 100ML FR-NL                            | 05410765001580 | BE                      | 100 ml | 62060023 |
| 02060112 | ELIMAX SHAMPOO 100ML HU-BG-SK-RO-CS-SR                | 05410765004758 | HU-BG<br>SK-RO<br>CS-SR | 100 ml | 62060023 |
| 02060125 | ANTI-BRUMM BY ELIMAX LAUS STOPP 2IN1<br>SHAMPOO 100ML | 05410765004789 | CH                      | 100 ml | 62060023 |
| 02060135 | PARASIDOSE SHAMPOING 2EN1 100ML                       | 05410765004796 | FR                      | 100 ml | 62060023 |

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