

The management system of

Oystershell NV

Nijverheidsweg 10
9820 Merelbeke, Belgium

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on pages 2 and 3 of this certificate.

This certificate is valid from 09 June 2020 until 15 April 2022
and remains valid subject to satisfactory surveillance audits.
Issue 5, Certified since 21 March 2008
and first certified by SGS Belgium NV since 03 April 2019

Certification is based on reports numbered BE/PND 05/1358.GMD

Authorised by



SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LRMD0007 - Certificate CE1639 Annex B-4, EN rev. 02

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Oystershell NV

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 5

Detailed scope

**ELIMAX® Shampoo for head lice treatment based on suffocation
and dehydration of lice (and nits):**

- Afir Duo Shampoo
- Anti-Brumm By Elimax Laus Stopp 2in1 Shampoo
- Bevitamed Taishampoo
- Elimax Lausfrei Kombi Pack
- Elimax Shampoo
- Kp24 Rapid Shampoo
- Lincin Plus Shampoo
- Lincin Shampoo
- Mosquito 2in1 Shampoo
- Prioderm Shampoo Plus

**ELIMAX® Lotion for head lice treatment based on suffocation
and dehydration of lice (and nits):**

- Afir Duo Lotion
- Elimax Flussig-Gel
- Elimax® Lotion
- Elimax® Lotion Spray
- Lincin Plus Solution

Oystershell NV

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Issue 5

Detailed scope

Wound care gel

- Akutol hydrogel
- BepanGel Wundgel
- BepanGel Hojivý gél
- BepanJel Wound healing gel
- BepanGel sebkezelő gél
- Bepanthen
- BepanGel
- Bepanthen Wundgel / gel cicatrisant / Wundheilgel
- BiseptineCica
- Bevitamed Haavageeli
- Flamozil
- Foille Cicatrici
- Help4Skin Burn Healing
- Help4Skin Chronic wounds
- Help4Skin Gojenie Oparzen
- Help4Skin Gojenie Ran
- Help4Skin S.O.S.
- Help4Skin Wound Healing
- Kepraxin Gel repair
- Mitocare
- MoM Repair
- Nestosyl 3-in-1 wondgel
- Neutron Skin Care
- Osmo Soft
- Zoralan skin wound care
- Zoralan wound
- Bepanthol 4in1 Gel
- Biseptinecica Gel
- Dermatix Woundcare
- Help4Skin Burns

Liquid and pen for topical use in the treatment of nail fungus (onychomycosis)

- Excilor / Excilor Enriched
- Naylex

Liquid for topical use in the treatment of nail fungus (onychomycosis)

- Excilor Forte
- Excilor Ultra
- Active Cover
- Active Cover Light
- Nailner Active Cover

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.