

EC Certificate Full Quality Assurance System: Certificate BE19/819943435

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 21 April 2021 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 8. Certified since 21 March 2008

Certification is based on reports numbered BE/AND 05/1358.QMD

Authorised by

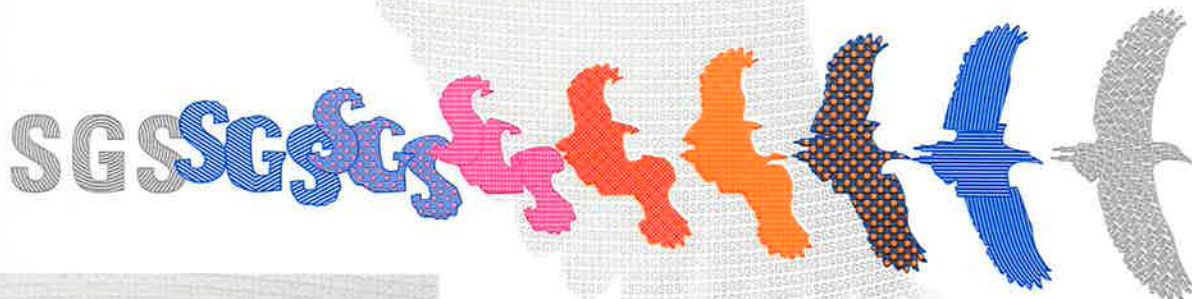
Global Medical Devices Head of Notified Body

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LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

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Oystershell NV

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 8
Detailed scope

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

- Aftir 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):

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

Wound care gel

- Akutol hydrogel
- BepanGel Wundgel
- BepanGel Hojivý gél
- BepanJel Wound healing gel
- BepanGel sebkezelő gél
- Bepanthen
- BepanGel
- Bepanthen Wondgel / 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

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- Zoralan wound
- Bepanthol 4in1 Gel
- Biseptinecica Gel
- Dermatix Woundcare
- Help4Skin Burns
- Osmo Soft Cicatrisant

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
- Active Cover Red

Hydrogel pen for the protection and pain relief of ulcers, small wounds or inflammatory lesions in the mouth

- Zoralan Pen
- Pyralpen
- Pyralvex Pen
- Isy calm
- Booth mouth ulcer gel
- Oralan pen
- Biopolymer

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.