FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS (FAMHP)

FREE SALE CERTIFICATE

Medical devices (MD)

N° of Certificate: 000633 16-03-20

Exporting (certifying) country: **Belgium**

Importing (requesting) country: Sri Lanka

SECTION TO BE COMPLETED BY THE APPLICANT OF THE CERTIFICATE

1. Name and form of product:

For class I, system and procedure pack and custom made MD, please provide the notification number

Please refer to Annex to EC Declaration of Conformity

1.1. Grouping according to Directive 93/42/EC: ○ I ○ Is/Im ○ I + Is/Im ○ IIa ◉ IIb ○ III
○ System and procedure pack ○ Custom made

1.2. Qualitative and quantitative composition or description (according to the type of the device):
The qualitative and quantitative compositions are indispensable if the device is in the form of a solution, cream, gel .....

Please refer to Annex to EC Declaration of Conformity

1.3. Does the product contain animal substances? No

If yes, which animal substance?

1.4. Does the product contain medicinal substances? No

If yes, which medicinal substance?

1.5. Does the product contain radioactive substances? No

If yes, which radioisotope and how much Becquerel?

1.6. Is this product authorized to be placed on the market for use in the exporting country? Yes

1.7. Is this product actually on the market in the exporting country? No

1.8. Does the exported product carry the CE mark according to Directive 93/42/EC? Yes

2. Information regarding the manufacturer:

2.1. Manufacturer (according to the definition of Directive 93/42/EC): name and address:

Greens Surgicals Pvt. Ltd. Plot No. 508 - 512, Savli Industrial Estate, GIDC Manjusar, Vadodara - 391 775, Gujarat, India

2.2. Applicant for certificate:

(EC REP) Obelis s.a. Bd General Wahis 53, 1030 Brussels, Belgium

2.3. Name and number of the Notified Body (if applicable): DNV GL Presafe AS n. 2460

2.4. Has the manufacturer been certified to be in compliance with ISO 9000/ EN 13485 standards? Yes

If yes state the name of the organisation that delivered the certificate: DNV GL Presafe AS

If no, please explain:

GREFFE DU COMMERCE ET D'INDUSTRIE DE BRUXELLES
27 -03- 2020
KAMER VOOR HANDEL EN NIJVERHEID VAN BRUSSEL

.VED FOR THE ADMINISTRATION

.nedical device as described above is presumed to meet the applicable provisions of Council Directive 3/42/EEC and can be placed on the market in the exporting country.

Address of certifying authority:	FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS EUROSTATION II, Victor Hortaplein 40 bus 40, 1060 BRUSSELS (BELGIUM) Telephone n°: +32 2 528.40.00
Date: 16 MAART 2020 Stamp:	Name of authorized person: Xavier De Cuyper Chief Executive Officer P.O. Hugues MALONNE Directeur général - DG POST

afmps fagg

EMBASSY OF THE DEMOCRATIC SOCIALIST REPUBLIC OF SRI LANKA BELGIUM

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LEGALISATIE - LEGALISATION - LEGALISATION

Gezien voor de legalisatie van de handtekening van :
Vu pour légalisation de la signature de :
Gesehen zur Legalisation der Unterschrift von :
Malonne Hugues

Onder Nr./Sous le n°/Unter Nr. : *200349356381*

Te/A/In : ***Brussel/Bruxelles/Brüssel*** Op/Le/Am : *27/03/2020*

Stempel/Sceau/Stempel: Ondertekening/Signature/Unterschrift:

Veldeman Martine

Document/Document/Dokument ***Attest/certificaat/Attestation/certificat/Bescheinigung***

Prijs/Prix/Preis: *20* EUR

Deze legalisatie waarborgt de authenticiteit van de inhoud van het document niet
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https://apphost.ejustice.fgov.be

I hereby certify that without any commitments to its contents, the signature appearing hereon is that of the duly authorized officer.

Competent Authority
for Ambassador
Embassy of the Democratic Socialist Republic of Sri Lanka in Belgium

Date 30.03.2020 B/cons/09/20/13 No.....

CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES

27-03-2020

KAMER VOOR HANDEL EN NIJVERHEID VAN BRUSSEL