FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS (FAMHP)

FREE SALE CERTIFICATE

Medical devices (MD)

N° of Certificate: 000049 20-11-19

Exporting (certifying) country: **Belgium**

Importing (requesting) country: Philippines

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:

CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES
27-11-2019
KAMER VOOR HANDEL EN NIJVERHEID VAN BRUSSEL

RESERVED FOR THE ADMINISTRATION

The medical device as described above is presumed to meet the applicable provisions of Council Directive 93/42/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: 20 NOV. 2019

Stamp:

Agence Fédérale des Médicaments et des Produits de Santé (AFMPS)

afmps fagg

Name of authorized person:

Xavier De Cuyper
Chief Executive Officer

P.O. Hugues MALONNE,
Directeur général - DG POST.

Aliona Neagu

GREFFE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES
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