

FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS (FAMHP)

FREE TRADE CERTIFICATE

N° of Certificate:

Exporting (certifying) country: **Belgium**

Importing (requesting) country: **Egypt**

000521-04-17

SECTION TO BE COMPLETED BY THE APPLICANT OF THE CERTIFICATE

1. Name and form of product: *Please refer to the Annex to the EC Declaration of Conformity*

1.1. Classification according to Council Directive 93/42/EEC: **IIb**

1.2. Qualitative and quantitative composition or description (according to the type of the device):

Please refer to the Annex to the 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 directive EEC/93/42? **YES**

2. Information regarding the manufacturer:

2.1. Manufacturer (according to the definition of Council Directive 93/42/EEC): **Greens Surgicals Pvt. Ltd., Plot No. 508-512, Savli Industrial Estate, GIDC, Manjusar, Vadodara - 391 775, Gujarat, India**

2.2. Applicant for certificate: **Obelis s.a., Bd Général Wahis 53, 1030 Brussels**

2.3. Name and number of the Notified Body (if applicable): **DNV GL Business Assurance Norway AS (0434)**


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

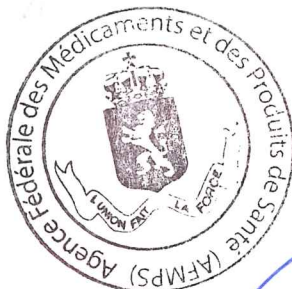
If yes state the name of the organisation that delivered the certificate: **DNV GL Business Assurance Norway AS**

If no, please explain:

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: 21 APR. 2017	Name of authorized person: Xavier De Cuyper Chief Executive Officer P.O. Hugues MALONNE, Directeur général - DG POST: 
Stamp:	



afmps
fagg

27-04-2017

Caroline Dewet

NOTED by the Brussels Chamber of Commerce

27 AVR. 2017
Brussels, the



سفارة جمهورية مصر العربية
Bruxelles
في مدينة
Chau de Velde
أصديق على صحة توقيع السيد
SPF Bti وخاتم MKE
دون أدنى مسئولية على القنصلية فيما يخص محتويات الوثيقة
رقم التتبع 2965
بالعملة المصرية
بالعملة المحلية
القنصل العام
29 AVR. 2017

B 00073030



B 00073030

LEGALISATIE - LEGALISATION - LEGALISATION

Gezien voor de legalisatie van de handtekening van:

Vu pour la légalisation de la signature de:

Gesehen zur Legalisation der Unterschrift von:

Malonne, Hugues

Onder nr./Sous le n°/Unter Nr. : 9805403214395400

Tel/A /In : Brussel/Bruxelles/Brüssel

Op/Le/ Am : 27/04/2017

Zegel/Sceau/Siegel

Ondertekening/Signature/Unterschrift

Jan Van de Velde

Document/Document/Dokument : Attest/Attestation/Bescheinigung

Prijs/Prix/ Preis : 20 EUR

Deze legalisatie waarborgt de authenticiteit van de inhoud van het document niet.
Cette légalisation ne garantit pas l'authenticité du contenu du document.
Diese Legalisation dient nicht dem Beweis der Authentizität des Inhalts des Dokuments.
Deze legalisatie controleren? Vérifier cette légalisation? Diese Legalisation überprüfen?
<http://legalweb.diplomatie.be>



GREENS SURGICALS (P) LTD.

ISO 13485 / 2012 Certified

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Vadodara 391775 (Gujarat)
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Web Site : www.greensurgicals.com
E-mail : info@greensurgicals.com
CIN : U24233DL2006PTC156927



EC DECLARATION OF CONFORMITY

We, **Greens Surgicals Pvt. Ltd.**, hereby declare under our own responsibility that the following products:

Please refer to the **Annex to EC Declaration of Conformity** meet the provisions of the Council Directive 93/42/EC and the essential requirements which apply to them.

The abovementioned devices have been classified as class **IIB** devices.

This declaration is supported by the Quality Management System certification No. 203369-2016-AQ-IND-NA issued by DNV GL Business Assurance Norway AS, Det Norske Veritas AS, Veritasveien 1, 1322 Hovik, Norway.

This declaration is based on the conformity assessment of products to the requirements of Annex II excluding section 4 according to the EC Conformity Certificate No. 203370-2016-CE-IND issued for the first time on 25/10/2016 and delivered by DNV GL Business Assurance Norway AS, Det Norske Veritas AS, Veritasveien 1, 1322 Hovik, Norway.

This Declaration is valid for all products concerned bearing the CE mark and manufactured by the above entitled "Manufacturer".

<Manufacturer's Signature>

DR. VINAY KUMAR
DIRECTOR

Issue place VADODARA, India
and date 18/03/2017,
<Stamp>



European Authorized Representative:



Registered Address:
Obelis s.a.

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Representative: Mr. Gidon ELKAYAM (CEO)

