FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS (FAMHP)

FREE TRADE CERTIFICATE

N° of Certificate: 000521-04-17
Exporting (certifying) country: **Belgium**
Importing (requesting) country: **Egypt**

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**

Brussels, the 27 AVR. 2017

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: Agence Fédérale des Médicaments et des Produits de Santé (AFMPS)	afmps fagg 27-04-2017	

Caroline Dewet

سفارة جمهورية مصر العربية

فى مدينة Bruxelles

أصدق على صحة توقيع السيد Jan de Velde

SPF BZ وخاتم MAE

دون أدنى مسئولية على القنصلية فيما يختص بمحتويات الوثيقة

رقم التصديق 2965

الرسم المحصل 80 €

بالعملة المصرية

بالعملة المحلية

القنصل العام

26 AVR. 2017

EMBASSY OF A.R.E. CONSULATE SECTION BRUXELLES

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*

Op/Le/ Am : *27/04/2017*

Te/A /In : *Brussel/Bruxelles/Brüssel*

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

EGYPT جمهورية مصر العربية 5

EGYPT مصر 141.50 L.E ١٤١٫٥٠ جنيه تصديق تجارى

S SURGICALS (P) LTD.

E, ISO 13485 / 2012 Certified

508-512, GIDC, Savli Industrial Estate,
sar, Vadodara 391775 (Gujarat)
e : +91-02667-264888
b Site : www.greensurgicals.com
-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 and date: VADODARA, India 18/03/2017,
<Stamp>

GREENS SURGICALS (P) LTD. BARODA-INDIA

European Authorized Representative:

CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES
27-04-2017
KAMER VOOR HANDEL EN NIJVERHEID VAN BRUSSEL

Registered Address:
Obelis s.a.
Bd. Général Wahis 53
B-1030 Brussels, Belgium
Phone: 32.2.732.59.54
Fax: 32.2.732.60.03
E-mail: mail@obelis.net
Representative: Mr. Gideon ELKAYAM (CEO)

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