

FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS (FAMHP)

FREE TRADE CERTIFICATE

0003 21-04-17

N° of Certificate  
 Exporting (certifying) country: **Belgium**  
 Importing (requesting) country: **Iran**

**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**


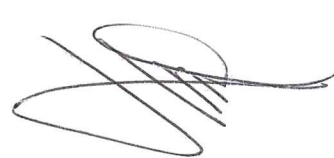
**2. Information regarding the manufacturer:**

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

**afmps fagg**  
 CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES  
 27-04-2017  
  
**Caroline Dewet**

SEEN  
 by the Brussels Chamber of Commerce  
 27 AVR. 2017  
 Brussels, the

نسخه اصلي

سفارت جمهوري اسلامي ايران-بروكسل

صحت مهر وامضاي وزارت امور خارجه بلژيک راکه برروي اين برگه  
بعلامت (X) مشخص شده، بدون توجه به مندرجات متن گواهي مینماید.  
بابت حقوق کنسولي سندشماره ۵۲۷۰۰۹۷۶ طی فیش شماره ۱۹۵۷ مبلغ  
۳۳۶ یورو دریافت شد.

شماره: ۱۵۴۹۲ تاریخ: ۱۳۹۶/۲/۱۳ ردیف ۱ از ۱ امضاء

Date : 03/05/2017 NO: 15492

فناور مطالب میرا بجاار - دیپلوم  
F. MATLOUB ABDOLJABBAR  
SECRETARY

B 00073029



B 00073029

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. : 9805653252700976

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

Op/Le/ Am : 27/04/2017

Zegel/Sceau/Siegel

Ondertekening/Signature/Unterschrift

*Jan Van de Velde*  
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

08-512, GIDC, Savli Industrial Estate,  
Vadodara 391775 (Gujarat)  
+91-02667-264888  
Site : www.greensurgicals.com  
mail : info@greensurgicals.com  
IN : U24233DL2006PTC156927



## EC DECLARATION OF CONFORMITY

We, *Greens Surgical 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.

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](mailto:mail@obelis.net)

Representative: Mr. Gideon ELKAYAM (CEO)