

FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS (FAMHP)

FREE TRADE CERTIFICATE

N° of Certificate: **000421-04-17**  
 Exporting (certifying) country: **Belgium**  
 Importing (requesting) country: **Marocco**

**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**

**SEEN**  
 by the Brussels Chamber of Commerce  
 Brussels, the 27 APR. 2017

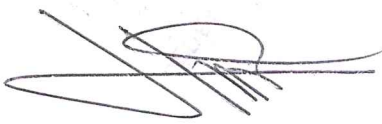





**2. Information regarding the manufacturer:**

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

**Caroline Dewet**

B. 00073031



B 00073031

**APOSTILLE**

(Convention de La Haye du 5 octobre 1961)

1. Land/Pays/Land : **BELGIË – BELGIQUE – BELGIEN.**

2. Deze openbare akte is ondertekend door :  
Le présent acte public a été signé par : **Malonne, Hugues**  
'Diese öffentliche Urkunde ist unterschrieben von:

3. Handelend in hoedanigheid van : **Directeur-generaal/directrice**  
Agissant en qualité de : **générale/Geschäftsführender Direktor**  
In seiner/ihrer Eigenschaft als:

4. Is voorzien van het zegel van : **Belgische Instelling/Institution**  
Est revêtu du sceau de : **Belge/Belgische Institution**  
Sie ist versehen mit dem Siegel des/der: **Brussels**

**Voor echt verklaard / Attesté / Bestätigt**

5. **Te Brussel/A Bruxelles/In Brüssel** 6. Op/Le/Am : **27/04/2017**

7. Door FOD Buitenlandse Zaken, Buitenlandse Handel en Ontwikkelingssamenwerking  
Par le SPF Affaires étrangères, Commerce extérieur et Coopération au Développement  
Durch FOD Auswärtige Angelegenheiten, Außenhandel und Entwicklungszusammenarbeit

8. Onder Nr. / Sous le n° / Unter Nr. : **9805596995648932**

9. Stempel/Sceau/Stempel : 10. Ondertekening/Signature/ Unterschrift :

Jan Van de Velde

Prijs/Prix/ Preis : **20** EUR

Deze Apostille waarborgt de authenticiteit van de inhoud van het document niet.  
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<http://legalweb.diplomatie.be>





# GREENS SURGICALS (P) LTD.

ISO 13485 / 2012 Certified

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Vadodara 391775 (Gujarat)  
+91-02667-264888  
e : www.greensurgicals.com  
: info@greensurgicals.com  
: 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>

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



DR. VINAY KUMAR  
DIRECTOR

European Authorized Representative:



Registered Address:

Obelis s.a.  
Bd. Général Wahis 53  
B-1030 Brussels, Belgium  
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Representative: Mr. Gideon



Manufacture & Exporter of : ORTHOPAEDIC & MAXILLOFACIAL IMPLANTS & INSTRUMENTS