



FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS (FAMHP)

# FREE SALE CERTIFICATE

## Medical devices (MD)

N° of Certificate:

00005120-11-19

Exporting (certifying) country: **Belgium**

Importing (requesting) country:

### 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

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 .....*

1.3. Does the product contain animal substances?

If yes, which animal substance?

1.4. Does the product contain medicinal substances?

If yes, which medicinal substance?

1.5. Does the product contain radioactive substances?

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?

1.7. Is this product actually on the market in the exporting country?

1.8. Does the exported product carry the CE mark according to Directive 93/42/EC?

#### 2. Information regarding the manufacturer:

2.1. Manufacturer (according to the definition of Directive 93/42/EC): name and address:

2.2. Applicant for certificate:

2.3. Name and number of the Notified Body (if applicable):

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




If yes state the name of the organisation that delivered the certificate:


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:	20 NOV. 2019	Name of authorized person:
Stamp:		Xavier De Cuyper Chief Executive Officer
		 P.O. Hugues MALONNE, Directeur général - DG POST.


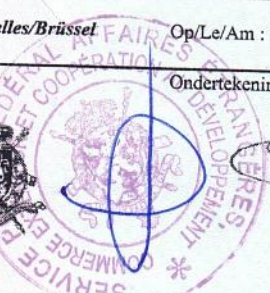
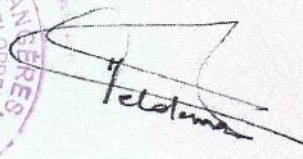
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**LEGALISATIE - LEGALISATION - LEGALISATION**

Gezien voor de legalisatie van de handtekening van :  
Vu pour légalisation de la signature de :  
Gesehen zur Legalisation der Unterschrift von :  
**Malonne Hugues**

Onder Nr./Sous le n°/Unter Nr. : 191118640611


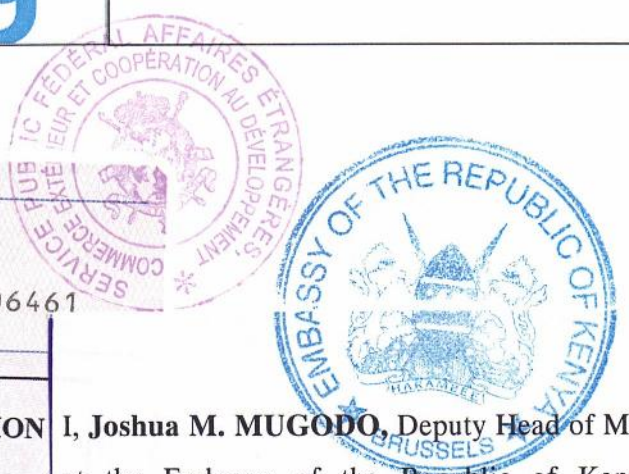
Te/A/In : Brussel/Bruxelles/Brüssel Op/Le/Am : 29/11/2019

Stempel/Sceau/Stempel:   Ondertekening/Signature/Unterschrift:  
  
Veldeman Martine

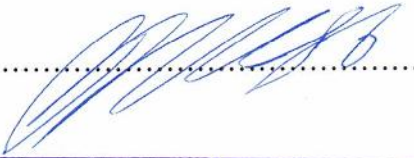
Document/Document/Dokument **Attest/certificaat/Attestation/certificat/Bescheinigung**

Prijs/Prix/Preis: 20 EUR

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<https://legalisatiediplomatie.be>

I, **Joshua M. MUGODO**, Deputy Head of Mission at the Embassy of the Republic of Kenya Brussels, do hereby certify that the signature subscribed hereinabove is that of **VELDEMAN Martine**, in testimony whereof I have hereunto my hand and the stamp of the Embassy, this 4<sup>th</sup> day of DECEMBER, 2019

Signature: 

**Aliona Neagu**  
