FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS (FAMHP)

FREE SALE CERTIFICATE

Medical devices (MD)

N° of Certificate: 000009 19-02-20

Exporting (certifying) country: **Belgium**

Importing (requesting) country: Thailand

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

Minze Uroflowsystem: Homeflow & Hospiflow, Notification number BE/CA01/1-16108-00001-CLI

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 .....

Uroflow system, consisting of a device and a software app, for measuring uroflows at the patient's home or in a professional setting, recording a voiding diary and transferring the results to the urologists or other medical specialists for diagnosis.

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? Yes

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

2. Information regarding the manufacturer:

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

Minze NV, Offerandestraat 1, 2060 Antwerpen, Belgium

2.2. Applicant for certificate:

Minze NV, Offerandestraat 1, 2060 Antwerpen, Belgium

2.3. Name and number of the Notified Body (if applicable): SGS Belgium NV, NB number 1639

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: SGS Belgium NV, NB number 1639

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: 19 FEB. 2020		Name of authorized person:
Stamp: Agence Fédérale des Médicaments et des Produits de Santé (AFMPS)	afmps fagg	Xavier De Cuyper Chief Executive Officer P.O. Hugues MALONNE, Directeur général - DG POST

Minze
health at home

EC DECLARATION OF CONFORMITY

We,

Minze NV, Offerandestraat 1, 2060, Antwerp, Belgium

hereby declare under our sole responsibility that the CE marked product to which this declaration relates,

Minze Uroflowsystem: Homeflow & Hospiflow

has been classified as Class I m, according to Annex IX, rule 12 with measuring function.

And is in conformity with the essential requirements and provisions of the Council Directive 93/42/EEC concerning medical devices as amended by Directive 2007/47/EC

And is conformity with the relevant harmonised standards:

- EN 60601-1:2006 +A1:2013 "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance"
- EN 60601-1-2:2007/AC:2010 "Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic
- EN62304:2006 "Medical device software - Software life-cycle processes"
- EN60601-1-11:2010 "Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical

and is subject to the procedure set out in Annex *II*, excl. section 4 of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC

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

This declaration is made on base of the quality assurance certificate

N°. BE18/819942887
delivered bv Notified Body n° 1639, SGS Belgium nv
on: 16/03/2018

This certificate is valid for devices released from the following site:

UNITRON SYSTEMS B.V.
Schansestraat 7-9
4515 RN IJzendijke

Date : 22/03/2018
Name : Jiri Vermeulen
Function : CEO

Signature :

Federaal agentschap voor geneesmiddelen en gezondheidsproducten
Eurostation II - Victor Hortaplein 40/40
1060 BRUSSEL
www.fagg.be

DG POST / Gezondheidsproducten / Medische hulpmiddelen

Afzender : Elodie Delplace

Tel. : 02/ 528 40 00
e-mail : meddevfagg.be

Minze NV
Offerandestraat, 1
2060 Antwerpen

Uw bericht van	Ons kenmerk	Datum	Indicateur
02/05/2018	FAGG/2019/XDC/DEE/16108	26 JULI 2019	1082192 – 1

Betreft: kennisgeving door de fabrikant van het in de handel brengen van medische hulpmiddelen van klasse I, conform artikel 10 van het K.B. van 18 maart 1999 betreffende de medische hulpmiddelen.

Mevrouw, Mijnheer,

Ik meld u de goede ontvangst van uw kennisgeving inzake het in de handel brengen van een medisch hulpmiddel, zoals beschreven in bijlage.

Uw kennisgeving van 02/05/2018 is geregistreerd onder het nummer:

BE/CA01/1-16108-00001-CLI

Dit nummer is geldig tot 13/03/2023 volgens het certificaat afgeleverd door de Notified Body 1639 - SGS Belgium NV

Dit ontvangstbericht is in geen geval een goedkeuring van de kwalificatie en de indeling van de klasse van het betreffende medisch hulpmiddel noch van hun overeenstemming aan de essentiële eisen volgens de bijlage I van het Koninklijk besluit van 18 maart 1999 betreffende de geneeskundige hulpmiddelen.

Elke wijziging aan de gegevens meegedeeld in het kader van deze kennisgeving moet binnen de 15 dagen meegedeeld worden aan het Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten.

Met de meeste hoogachting,

De Administrateur-generaal

Xavier De Cuyper

Productlijst

Notificatienummer	Beschrijving van het product
BE/CA01/1-16108-00001-CLI	Uroflow system, consisting of a device and a software app, for measuring uroflows at the patient's home or in a professional setting, recording a voiding diary and transferring the results to the urologists or other medical specialist for diagnosis.

Commerciële naam

Minze Homeflow

Minze Hospiflow

Fabrikant :

Minze NV
Offerandestraat, 1
2060 Antwerpen
BELGIUM

EC Certificate Full Quality Assurance System: Certificate BE18/819942887

The management system of

Minze NV

Offerandestraat 1
2060 Antwerpen, Belgium

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Metrological aspects only – Restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements.

Uroflow system:
System, consisting of a device and a software app, for measuring uroflows at the patient's home or in a professional setting, recording a voiding diary and transferring the results to the urologist or other medical specialist for diagnosis.

This certificate is valid from 16/03/2018 until 13/03/2023
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 16/03/2018.
Re certification audit due before 06/04/2020.

Certification is based on reports numbered BE/AMD 17/1040.QM/D

Authorised by

Pieter Weterings
Certification Manager

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

Certificate BE18/819942886

The management system of

Minze NV

Offerandestraat 1
2060 Antwerpen, Belgium

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activites

Design, development, manufacture, sales and distribution of a uroflow system, consisting of a device and a software app, for measuring uroflows at the patient's home or in a professional setting, recording a voiding diary and transferring the results to the urologist or other medical specialist for diagnosis.

This certificate is valid from 25/10/2018 until 13/03/2021
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 14/03/2018.
Re certification audit due before 13/02/2021.

Authorised by

Pieter Weterings
Certification Manager
SGS Belgium NV
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

Accreditation Number
008-CMS
EN ISO/IEC 17021-1:2015

SGS Belgium 13485-2 0308