EU Quality Management System Certificate BE23/00000279

The management system of

Minze NV

Lange Gasthuisstraat 29 bus 15, 2000 Antwerpen, Belgium
SRN Number: BE-MF-000022123

has been assessed and certified as meeting the requirements of

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

For the following products

The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 09 September 2025 until 27 September 2028 and remains valid subject to satisfactory surveillance audits.

Recertfication audit due before 27 March 2028

Issue 4. Certified since 27 September 2023

Authorised by
Virginie Siloret
Global Medical Device
Certification Manager

SGS Belgium NV NB1639

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Minze NV

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

Class: Im
MDS1010
Minze Uroflow: Uroflowmeter device for measuring uroflows at the patient's home or in a professional setting.

[Basic UDI-DI 5430000676934A]

Class IIa
MDA0315, MDS1009
Minze Platform: Software platform to collect and present uroflow data, recording a voiding diary and transferring the results to the urologist or other medical specialist for diagnosis.

[Basic UDI-DI 54300006769146]

Conditions for & limitation to the validity of the certificate:
For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available “on request" per email to NB1639@sgs.com.

Limitation: N/A

Certification is based on following reports: - BE/AMD/7/1040.QMD - CTC 3.21 + TFR 3.3 + CTC
Previous certificate number: N/A
Change in between this certificate and previous one: Removal of MDN1201 code.