EU Quality Management System Certificate BE25/00000286

The management system of

Mainit B.V.

Roode Wildemanweg 5 1521 PZ Wormerveer The Netherlands
SRN Number: NL-MF-000012155

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 04 November 2025 until 04 November 2030 and remains valid subject to satisfactory surveillance audits.
Recertification audit due before 04 May 2030

Issue 1. Certified since 04 November 2025

Authorised by
Virginie Siloret
Global Medical Device
Certification Manager

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EU Quality Management System Certificate BE25/00000286, continued

Mainit B.V.

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

Class IIa Device
MDN1204, MDS1001, MDS1008
Silver nitrate caustic applicator
[Basic UDI-DI: 87202994228ZVNTMAINITX5]

Silver nitrate caustic pencil
[Basic UDI-DI: 87202994228ZVNTMAINITPNGY]

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.

Certification is based on following reports: - BE/AMD/205429 - S2A 1.1 + TFR 1.2
Authorized representative name and address (if relevant): N/A
Previous certificate number: N/A
Change in between this certificate and previous one: N/A