

Declaration of Conformity

In accordance with Regulation (EU) 2017/745

1.0 Legal Manufacturer Details

Manufacturers Name: Mainit B.V.
Manufacturers Address: Roode Wildemanweg 5, 1521 PZ Wormerveer
SRN (Single Registration Number): NL-MF-000012155

2.0 Authorized Representative

Not Required – Legal Manufacturer based in The Netherlands which is an EU Member State.

3.0 Declaration to Regulation (EU) 2017/745

We hereby declare under our sole responsibility of Mainit B.V that the distributed CE marked products as listed below conform to applicable Annex I General Safety and Performance Requirements of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices.

Furthermore, the conformity assessment procedure in place for the devices referenced in section 5 follows the requirements of Annex IX of the Regulation (EU) 2017/745 and the related information is periodically reviewed by SGS Belgium NV, SGS House, Noorderlaan 87, 2030 Antwerp, Belgium. Certificate: BE25/00000286

Notified body number CE 1639.

Classification: Class IIa, Rule 4 and Rule 21 (Annex VIII)

This declaration is supported by the Quality Management System certification based on ISO 13485:2016 and the harmonized standard EN ISO 13485:2016. Quality Management System Certificate issued to Mainit B.V with certificate number BE25/00000044 by SGS Belgium NV, and applicable certification notice in accordance with their terms and conditions.

3.1 Additional Directives or Regulation

Not Applicable

3.2 Common specifications

Not Applicable

4.0 Intended purpose of the device:

4.1 Regulation (EU) 2017/745

The Mainit Zilvernitraatstift (Mainit Silver Nitrate Caustic Pencil and Caustic Applicator) is a Class IIa medical device intended for use by patients for the treatment of warts and verrucas by means of a caustic effect and by healthcare professionals for the treatment of warts, verrucas, the residual umbilical cord, hyper granulation, aphthous stomatitis, haemostasis of superficial bleeding and nosebleeds by means of a caustic effect. The device is intended for Short Term use to be used for local topical application to the skin (intact and damaged), mucus membrane of the mouth (but not past the pharynx) and nasal cavity. The Silver Nitrate Caustic Pencil is single patient use and intended for multiple applications. The Silver Nitrate Caustic Applicator is single use.

The Mainit Zilvernitraatstift (Mainit Silver Nitrate Caustic Pencil and Caustic Applicator) is not intended for use near eyes, on genital warts or on sensitive areas of the body.

Use on children and vulnerable people should be only by an adult, a carer or a Healthcare Professional

5.0 Description of the devices

Basic UDI-DI: 87202994228ZVNTMAINITX5					
Product name/Trade name	Product Code	UDI-DI Reference	Added on DoC	EU Market Exit Date ¹	EMDN Codes
Mainit Zilvernitraatstift Caustic Applicator 95% w/w,	226506	8720299422803	06/11/2025	n/a	A99
Mainit Zilvernitraatstift Caustic Applicator 75% w/w	226505	8720299422810	06/11/2025	n/a	A99
Mainit Zilvernitraatstift Caustic Applicator 95% w/w	2265061	8720299422841	06/11/2025	n/a	A99
Mainit Zilvernitraatstift Caustic Applicator 75% w/w	2265051	8720299422858	06/11/2025	n/a	A99

Basic UDI-DI: 87202994228ZVNTMAINITPNGY					
Product name/Trade name	Product Code	UDI-DI Reference	Added on DoC	EU Market Exit Date ¹	EMDN Codes
Mainit Zilvernitraatstift Caustic Pencil 40% w/w	226504	8720299422827	06/11/2025	n/a	A99
Mainit Zilvernitraatstift Caustic Pencil 95% w/w	226511	8720299422834	06/11/2025	n/a	A99

Notes

1. This is the date when a device is no longer placed on the EU Market.
2. EMDN codes description is in the table below.

EMDN Code	Description
A99	Devices for Administration, Withdrawal and Collection – Other

6.0 Declaration made on behalf of Legal Manufacturer by:

Date:	06 NOV 2025
Place:	Roode Wildemanweg 5, 1521 PZ Wormerveer. Netherlands
Signature:	
Name:	Theo Post
Position:	Owner/Director