

The management system of

Mona Lisa N.V.

Kapelstraat 1
3540 Herk-de-Stad, 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

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 03 July 2020 until 04 July 2022
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 29 July 1996
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered BE/AND 06177

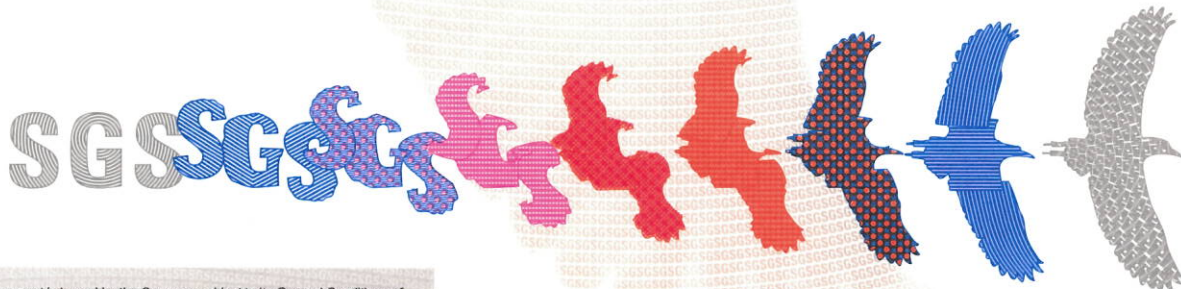
Authorised by

SGS Belgium NV, Notified Body 1639

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LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

Page 1 of 2



Mona Lisa N.V.

Directive 93/42/EEC
on medical devices, Annex II (excluding Section 4)

Issue 2

Detailed scope

**Sterile Intrauterine devices, supplied with or without Hysterometer Size 12
(in a separate sterile pouch)**

**Mona Lisa® NT Cu380
Mona Lisa® NT Cu380-Mini
Mona Lisa®CuT 380A
Mona Lisa®CuT 380A QL
Mona Lisa® Cu 375
Mona Lisa® Cu 375 SL
Mona Lisa® ST Cu 300**

**CU-Safe® T300
Neo-Safe® T CU 380
Neo-Safe® T CU 380-Mini**

**T-Safe® CU 380A
T-Safe® CU 380A QL**

**Mithra®-Sert 380
Mithra®-T 380
Mithra®-Load 375
Mithra®-Flex 300**

**Multi-Safe® CU375
Multi-Safe® CU375 Short**

T-Protect® CU 380A

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

