

EC Design Examination Certificate: Certificate BE19/819943788

Mona Lisa N.V.

Kapelstraat 1, 3540 Herk-de-Stad, Belgium

Device Identification:

**Sterile Mona Lisa® CuT 380A, T-Safe® CU 380A, T-Protect® CU 380A,
Mona Lisa® CuT 380A QL, T-Safe® CU 380A QL, and Mithra®-T 380
Intrauterine devices.**

**All the above IUD's are supplied with or without Hysterometer size 12
in a separate sterile pouch.**

Intended Purpose of Device:

**Copper-containing intrauterine devices intended for long-lasting
reversible female contraception**

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on Medical Devices, Annex II, Section 4

It is certified that the manufacturer's design dossier (and product, where applicable) for the above device has been examined and, based on the evidence submitted, it is considered that the device conforms to the relevant Essential Requirements of EC Directive 93/42/EEC.

This certificate is issued in conjunction with a certificate covering the full quality assurance system to Annex II, which must be subject to satisfactory surveillance audits.

This certificate is valid from 22 May 2020 until 20 April 2023
Issue 2. Certified since 20 April 1998
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered BE/AND 202064 dated 06 April 2018

Addenda to that report have been issued on the following dates:

- | | |
|------------------|--|
| 13 November 2018 | The use of DuPont Tyvek® (MPTP) transition material |
| 12 August 2019 | Change of the address |
| 20 November 2019 | Addition of the new brand name |
| 08 January 2020 | Change to labelling to included specific reference to the product including a Size 12 Hysterometer |
| 06 May 2020 | Change of supplier for the polyamide (Nylon) withdrawal thread
Validation of a dedicated load ethylene oxide sterilization cycle at Sterigenics (Petit Rechain) |

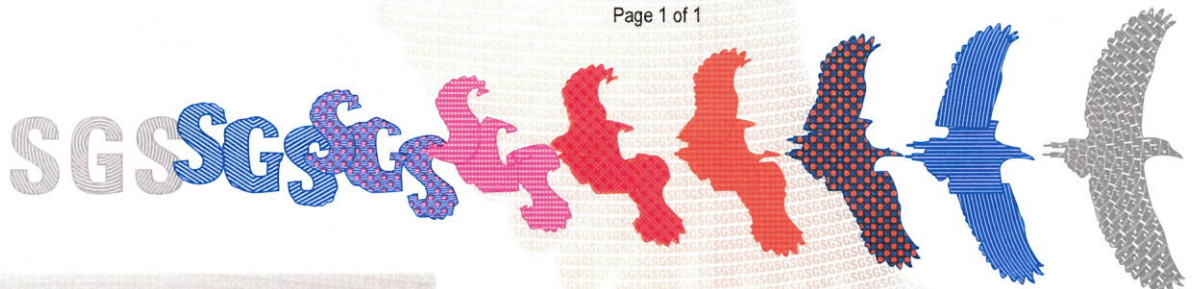
Authorised by

SGS Belgium NV, Notified Body 1639

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