

EC Design Examination Certificate: Certificate BE98/12708

Mona Lisa N.V.

Graaf de Theuxlaan 25 Bus 2, Heusden-Zolder, 3550, Belgium

Device Identification:

**Sterile Mona Lisa® CuT 380A, T-Safe® 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 06 February 2019 until 20 April 2023
Issue 19

Certification is based on report number(s) BE/AND 202064 dated 06 April 2018

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

<u>Addendum Date</u>	<u>Reason for Addendum</u>
13 November 2018	The use of DuPont Tyvek (MPTP) transition material

Authorised by

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