

EC Design Examination Certificate: Certificate BE03/59306

Mona Lisa N.V.

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

Device Identification:

**Sterile Mona Lisa® NT Cu380, Neo-Safe® T CU 380, Mithra® -Sert 380,
Mona Lisa® NT Cu380-Mini and Neo-Safe® T CU
380-Mini Intrauterine Devices**
The Intrauterine Devices may be supplied with or without a Size 12
Hysterometer

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 25 May 2023
Issue 13

Certification is based on report number(s) BE/AND 208591 dated 27 February 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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