

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 14 May 2018 until 25 May 2023 Issue 12

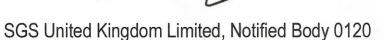
Certification is based on report number(s) BE/AND 208591 dated 27 February 2018

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

Addendum Date N/A Reason for Addendum

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Authorised by

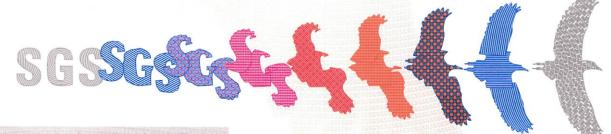


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