EC Design Examination Certificate: Certificate BE19/819943787



Mona Lisa N.V.

Kapelstraat 1, 3540 Herk-de-Stad, 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

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 25 May 2023 Issue 2. Certified since 25 May 2003 and first certified by SGS Belgium NV since 16 February 2020

Certification is based on reports numbered BE/AND 208591 dated 27 February 2018

Authorised by

SGS Belgium NV, Notified Body 1639

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Certificate BE19/819943787 continued



Mona Lisa N.V.

Directive 93/42/EEC

on Medical Devices, Annex II, Section 4

Issue 2

Certification is based on reports numbered BE/AND 208591 dated 27 February 2018

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

Addendum Date 13 November 2018 12 August 2019 08 January 2020

06 May 2020

Reason for Addendum
The use of DuPont Tyvek (MPTP) transition material
Change of the address
Change to labelling to included specific reference
to the product including a Size 12 Hysterometer
Change of supplier for the polyamide (Nylon) withdrawal thread
Validation of a dedicated load ethylene oxide
sterilization cycle at Sterigenics (Petit Rechain)





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