

# 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

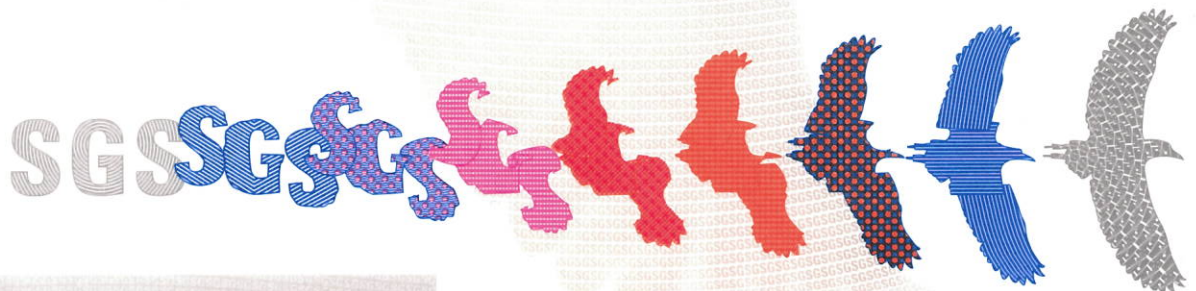
Authorised by

**SGS Belgium NV, Notified Body 1639**

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## 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:

<u>Addendum Date</u>	<u>Reason for Addendum</u>
13 November 2018	The use of DuPont Tyvek® (MPTP) transition material
12 August 2019	Change of the address
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)

