EC Certificate Full Quality Assurance System: Certificate BE19/819943784

The management system of

# Mona Lisa N.V.

Kapelstraat 1
3540 Herk-de-Stad, Belgium

has been assessed and certified as meeting the requirements of

# Directive 93/42/EEC

**on medical devices, Annex II (excluding Section 4)**

For the following products

**The scope of registration appears on page 2 of this certificate.**

This certificate is valid from 03 July 2020 until 04 July 2022
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 29 July 1996
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered BE/AND 06177

Authorised by

SGS Belgium NV, Notified Body 1639
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# Mona Lisa N.V.

# Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 2

Detailed scope

**Sterile Intrauterine devices, supplied with or without Hysterometer Size 12 (in a separate sterile pouch)**

**Mona Lisa® NT Cu380**
**Mona Lisa® NT Cu380-Mini**
**Mona Lisa®CuT 380A**
**Mona Lisa®CuT 380A QL**
**Mona Lisa® Cu 375**
**Mona Lisa® Cu 375 SL**
**Mona Lisa® ST Cu 300**

**CU-Safe® T300**
**Neo-Safe® T CU 380**
**Neo-Safe® T CU 380-Mini**

**T-Safe® CU 380A**
**T-Safe® CU 380A QL**

**Mithra®-Sert 380**
**Mithra®-T 380**
**Mithra®-Load 375**
**Mithra®-Flex 300**

**Multi-Safe® CU375**
**Multi-Safe® CU375 Short**

**T-Protect® CU 380A**

**Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.**