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 25 May 2021 until 04 July 2023
And remains valid subject to satisfactory surveillance audits.
Issue 4. Certified since 29 July 1996

Certification is based on reports numbered BE/AND 06177

Authorised by

Global Medical Devices Head of Notified Body

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 4

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

MI-MONA®-SERT 380
MI-MONA®-T 380
MI-MONA®-LOAD 375
MI-MONA®-FLEX 300
MI-MONA®-SERT 380 MINI

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.