EC Certificate Full Quality Assurance System: BE96/8075

The management system of

Mona Lisa N.V.

Graaf de Theuxlaan 25 Bus 2
3550 Heusden-Zolder, 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 24 April 2018 until 04 July 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 04 June 2020
Issue 15. Certified since 29 July 1996

Certification is based on reports numbered BE/AND 06177

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

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SGS CE 02 0315 M2

Mona Lisa N.V.

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 15

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® Cu250
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

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