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

SGS House Noorderlaan 87 2030 Antwerp Belgium t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

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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-Mini 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







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