EC Design Examination Certificate: Certificate BE19/819943789

Mona Lisa N.V.

Kapelstraat 1, 3540 Herk-de-Stad, Belgium

Device Identification:

Sterile Mona Lisa® Cu375, Multi-Safe® CU375, MI-MONA®-LOAD 375, Mona Lisa® Cu375 SL, Multi-Safe® CU375 Short, Mona Lisa® ST Cu300, MI-MONA®-FLEX 300 and CU-Safe® T300 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 requiremnts of

Directive 93/42/EEC

on Medical Devices, Annex II section 4

It is certified that the manufacture'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 conjuction 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 24 May 2021 until 24 May 2024

Issue 4

Certification is based on reports numbered BE/AND 201993 dated 21 May 2021

Addenda to that report have been issued on the following dates:

Addedum Date	Reason for Addendum
N/A	N/A

Authorised by

Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639

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