

EC Design Examination Certificate: Certificate BE97/10486

Mona Lisa N.V.

Kapelstraat 1, 3540 Herk-de-Stad, Belgium

Device Identification:

Sterile Mona Lisa® Cu375, Multi-Safe® CU375, Mithra®-Load 375, Mona Lisa® Cu375 SL, Multi-Safe® CU375 Short, Mona Lisa® ST Cu300, Mithra®-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 requirements of

Directive 93/42/EEC on Medical Devices Annex II, section 4

It is certified that the manufacturer'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 conjunction 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 17 January 2020 until 07 August 2022
Issue 21

Certification is based on reports numbered BE/AND 201993 dated 29th November 2017

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

Addendum Date	Reason for Addendum
25 May 2018	Device description and intended purpose amended for consistency
13 November 2018	The use of DuPont Tyvek® (MPTP) transition material
12 August 2019	Change of the address
08 January 2020	Change to labelling to included specific reference to the product including a Size 12 Hysterometer

Authorised by

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