EC Design Examination Certificate: Certificate BE97/10486

# Mona Lisa N.V.

Graaf de Theuxlaan 25 Bus 2, 3550 Heusden-Zolder, 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 above Intra Uterine Devices are supplied with or without a Size 12 Hysterometer**

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 06 February 2019 until 07 August 2022
Issue 19

Certification is based on report number(s) 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 |

Authorised by

SGS United Kingdom Limited, Notified Body 0120
202B Worle Parkway, Weston-super-Mare, BS22 6WA, UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS EC 01 0311