

EC DECLARATION OF CONFORMITY (version 18)

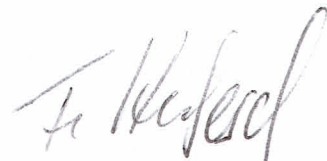
Mona Lisa N.V.
Kapelstraat 1
3540 Herk-de-Stad
Belgium

hereby declares under its sole responsibility, that the medical devices described hereafter

IUD type	Brand name	Reference number
Cu375	Mona Lisa® Cu375	REF 15375101
Cu375	Multi-Safe® CU375	REF 15375101
Cu375	MI-MONA®-LOAD 375	REF 15375101
Cu375 SL	Mona Lisa® Cu375 SL	REF 15375201
Cu375 SL	Multi-Safe® CU 375 short	REF 15375201
ST-Cu300	Mona Lisa® ST Cu300	REF 15300101
ST-Cu300	MI-MONA®-FLEX 300	REF 15300101
ST-Cu300	CU-Safe® T 300	REF 15300101

- GMDN Code: 46920
- has been classified as Class III (Annex IX Rule 14 and 13) and
- are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC
- are subject to the Design Examination Certificate No. **BE19/819943789** and EC Design Examination Report **BE/AND 201993** issued by Notified Body Number 1639, SGS Belgium NV, SGS House Noorderlaan 87, 2030 Antwerp, Belgium
- are subject to the procedure set out in Annex II of Directive 93/42/EEC under the supervision of Notified Body Number 1639, SGS Belgium NV, SGS House Noorderlaan 87, 2030 Antwerp, Belgium. Certificate No. **BE19/819943784**
- are in conformity with the requirements of the EN ISO 7439:2015

Herk-de-Stad, 19th of February 2021



Dr. Friederike Hrubesch-Mohringer
General Manager
on behalf of Mona Lisa N.V.