

EC DECLARATION OF CONFORMITY (version 17)

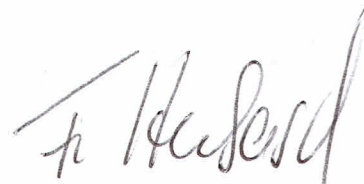
Mona Lisa N.V.
Kapelstraat 1
3540 Herk-de-Stad
Belgium

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

IUD type	Brand name	Reference number
CuT-380A		
CuT-380A(S)	Mona Lisa® CuT 380A	REF 15380101
	T-Safe® CU 380A	REF 15380101
	T-Protect® CU 380A	REF 15380101
CuT-380A-QL	Mona Lisa® CuT 380A QL	REF 15380201
	T-Safe® CU 380A QL	REF 15380201
	MI-MONA®-T 380	REF 15380201

- 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. **BE19/819943788** and EC Design Examination Report **BE/AND 202064** 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.