

## EC DECLARATION OF CONFORMITY (version 14)

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
NT Cu380	Mona Lisa <sup>®</sup> NT Cu380	REF 15380301
	Neo-Safe <sup>®</sup> T CU 380	REF 15380301
	MI-MONA <sup>®</sup> -SERT 380	REF 15380301
NT Cu380-Mini	Mona Lisa <sup>®</sup> NT Cu380-Mini	REF 15380401
	Neo-Safe <sup>®</sup> T CU 380-Mini	REF 15380401
	MI-MONA <sup>®</sup> -SERT 380 MINI	REF 15380401

- 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. **BE19/819943787** and EC Design Examination Report **BE/AND 208591** 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.