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

26 Apr 2023

Confirmation Letter Reference: CLNB1639 - BE/AND/06177+202064+208591+201993

To whom it may concern,

Confirmation of receipt of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Mona Lisa N.V.
Kapelstraat 1
3540 Herk-de-Stad
Belgium
SRN Number: BE-MF-000003642

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15th March 2023, this letter also confirms that:

- The manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry;
- The certificates expired after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

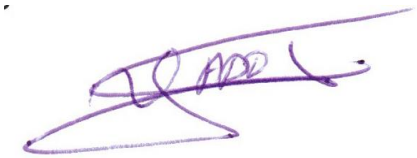
The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26th May 2026 for Class III custom-made implantable devices

SGS NB1639 - Confirmation letter Regulation (EU) 2023/607

- 31st December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31st December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31st December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body SGS Belgium NV 1639,



pp [Jérôme JADOT]

Virginie SILORET
Global Medical Device Certification Manager
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Devices covered by this letter:

Device name / Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Sterile Intrauterine devices, supplied with or without Hysterometer Size 12 (in a separate sterile pouch) Mona Lisa® NT Cu380 Mona Lisa® NT Cu380-Mini Mona Lisa®CuT 380A Mona Lisa®CuT 380A QL	Class III	N/A	BE19/819943784 (Issue 4), NB1639 Annex-II, excluding section 4

SGS NB1639 - Confirmation letter Regulation (EU) 2023/607

Device name / Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Mona Lisa® Cu 375 Mona Lisa® Cu 375 SL Neo-Safe® T CU 380 Neo-Safe® T CU 380-Mini T-Safe® CU 380A T-Safe® CU 380A QL MI-MONA®-SERT 380 MI-MONA®-T 380 MI-MONA®-LOAD 375 MI-MONA®-SERT 380 MINI Multi-Safe® CU375 Multi-Safe® CU375 Short T-Protect® CU 380A 426068395ML300375380IUDU5			
Device identification: Sterile Mona Lisa® NT Cu380, Neo-Safe® T CU 380, MI-MONA®-SERT 380, Mona Lisa® NT Cu380-Mini, MI-MONA®-SERT 380 MINI and Neo-Safe® T CU 380-Mini 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-	Class III	N/A	BE19/819943787 (Issue 3), NB1639 Annex-II, Section 4

SGS 1639 - Confirmation letter Regulation (EU) 2023/607

Device name / Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
lasting reversible female contraception 426068395ML300375380IUDU5			
Device Identification: Sterile Mona Lisa® CuT 380A, T-Safe® CU 380A, T-Protect® CU 380A, Mona Lisa® CuT 380A QL, T-Safe® CU 380A QL, and MI-MONA®-T 380 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 426068395ML300375380IUDU5	Class III	N/A	BE19/819943788 (Issue 3), NB1639 Annex-II, Section 4
Device Identification: Sterile Mona Lisa® Cu375, Multi-Safe® CU375, MI-MONA®-LOAD 375, Mona Lisa® Cu375 SL, Multi-Safe® CU375 Short 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-	Class III	N/A	BE19/819943789 (Issue 4), NB1639 Annex-II, Section 4

SGS NB(639) - confirmation letter Regulation (EU) 2023/607

Device name / Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
lasting reversible female contraception 426068395ML300375380IUDU5			

Confirmation Letter Revision History:

Date	NB internal reference traceable to each version of the letter	Action
2023/04/26	Version 1	Initial issue
2023/05/12	Version 2	Corrections
2023/05/24	Version 3	Corrected version, removal of three devices that will not proceed under MDR
2023/05/25	Version 4	Corrected version by CDM, removal in all MDD certificates of three devices "Mona Lisa® ST Cu 300" & "CU-Safe® T300" & "MI-MONA®-FLEX 300" since not included under MDR application

SGS NB1639 - Confirmation letter Regulation (EU) 2023/607