Certificate BE20/819944075

The quality management system of

SGS

Mona Lisa N.V.

Kapelstraat 1, 3540 Herk-de-Stad, Belgium

Facility number: F003342

has been assessed and certified as meeting the requirements of

MDSAP (ISO 13485:2016)

Australia: Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System

Canada: Medical Device Regulations SOR/98-282, Part 1

For the following activities

Design, development and manufacture of sterile intra-uterine contraceptive devices containing copper with or without sterile hysterometer, used in area of gynaecology.

This certificate is valid from Effective date 2024-01-30 until Expiry date 2026-07-04 and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 2020-10-07

Last certificate expiry date 2023-10-06 Recertification audit date 2023-09-14

Henderson

Authorised by

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SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at www.SGS.com.





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