

STATEMENT: EXTENSION OF MDD CERTIFICATES

We, Endomed srl located in Spigno Saturnia – Via Ugo La Malfa snc, 04020, hereby declare that conditions granted by Regulation (EU) 2023/607 are fulfilled for extension of the validity of MDD certificates IT280014-3, IT280018-4, IT280019-4, IT280020-4, IT304480-1, IT302169-1, IT300165-1 until December 2028.

In particular, Endomed srl declares that:

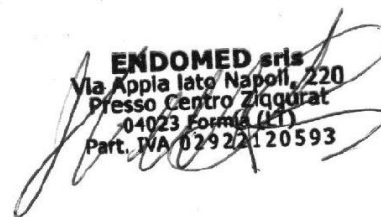
1. Before the date of expiry of the certificates, Endomed srl signed a written agreement with ICIM in accordance with Section 4.2, second subparagraph, of Annex VII to MDR for the conformity assessment.
2. The devices covered by MDD certificates IT280014-3, IT280018-4, IT280019-4, IT280020-4, IT304480-1, IT302169-1, IT300165-1 continue to comply with MDD.
3. During the extension period, no significant changes will be applied to the design and intended purpose of the medical devices covered by the extension.
4. The devices do not present an unacceptable risk to the health of safety of patients, users or other persons, or to other aspects of the protection of public health.
5. Endomed Srl complies with Article 10(9) of MDR regulation. For such Quality Management System, Endomed srl holds and ISO 13485:2016 certificate nr IT305660 issued by BUREAU VERITAS SPA.
6. The applications for certification under MDR and the technical documentation have been acknowledged by ICIM in 2022.

The devices covered by extension as following:

Urologic devices and instruments; Gynecology devices and instruments; arthroscopy devices and instruments; Ultrasonic scalpels (Unit and accessories); Semiflexible URS; Electrosurgical instruments; Electrosurgical units and accessories; Rigid endoscopes; Laparoscopic instruments (Forceps, Trocars, suction- irrigation devices).

Should you have any questions or comments, please do not hesitate to contact Endomed srl Regulatory Affairs department: s.giuliano@endomed srl.com.

Il legale Rappresentante



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