CERTIFICATE

The Certification Body TÜV Rheinland Italia S.r.l.

certifies, in accordance with the TÜV Rheinland Group procedures, that the Company

HS HOSPITAL SERVICE S.P.A.

Via Angela Vacchi 23/25 IT - 04011 Aprilia (Latina)

Via dei Bonificatori SNC IT - 04011 Aprilia (Latina)

Design and manufacturing of sterile and not sterile medical devices as needles for biopsy, aspiration, injection and surgical localization and related accessories, catheters, tubes and accessories for drainage and injection, elastomeric pumps for infusion, needles and kits for anesthesia and lumbar puncture, instruments, kits and accessories for surgery.

Design, manufacturing and servicing of electro-medical devices for microwave and radiofrequency thermoablation and accessories for thermoablation.

Trade of sterile and not-sterile, reusable, disposable medical devices.

Through an Audit, Report No. 28112235 001, proof has been furnished that the quality management system fulfils the requirements of the standard

UNI CEI EN ISO 13485:2016

Please refer to the Quality Manual for the details about the exclusions with respect to the requirements of the standard.

Certificate Registration No. 39 05 1041410.

This Certificate is valid from 2018-12-11 to 2021-12-12.

The reference date for all the next audits is (day-month): 12-12.

Milan, 2018-12-11. First Certification: 1998-10-30

The certification responsible: Daniele Ricchi

TÜV Rheinland Italia S.r.I., Via E. Mattei, 3 - I - 20010 Pogliano Milanese (MI)

This certificate does not represent proof that the statutory requirements of the Directives 93/42/EEC. 90/385/EEC or 98/79/EC have been fulfilled.



SGQ N° 083A SGA N° 052D

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC

Signatory of EA, IAF and ILAC Mutual Recognition Agreement



Management System EN ISO 13485:2016



