CERTIFICATE

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

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

ELEMASTER S.p.A.

Via Degli Artigiani 2 I - 23874 Montevecchia (LC)

has established and applies a quality management system for the following scope:

Manufacturing of electronic boards for medical equipments.

Assembling of diagnostic medical devices with customer specifications.

Through an Audit, Report No. 7974478040MCU06, 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 0931409/02.

This Certificate is valid from 2021-07-23 to 2024-06-16.

The reference date for all the next audits is (day-month): 16-04.

Milan, 2021-07-23. First Certification: 2011-05-05

The certification responsible: Daniele Ricchi TÜV Rheinland Italia S.r.I., Via E. Mattei, 3 - I - 20005 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° 083 A





