CERTIFICATE

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

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

FRANCESCO FRANCESCHETTI **ELASTOMERI S.R.L.**



Via Giulio Pastore n. 33/35 IT - 25040 Corte Franca (BS)

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

Design and manufacture of elastomeric and thermoplastic compounds for the medical fields.

Through an Audit, Report No. 28111767 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 0781504.

This Certificate is valid from 2018-09-11 to 2021-09-20.

The reference date for all the next audits is (day-month): 10-09.

Milan, 2018-09-11. First Certification: 2015-09-21

The certification responsible

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 deali Accordi di Mutuo

Signatory of EA, IAF and ILAC Mutual Recognition Agreement



Management System EN ISO 13485:2016

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