CERTIFICATE

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

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

MED ITALIA BIOMEDICA S.R.L.

Via P. Gobetti, 56R, IT - 16145 Genova (GE) Via Rio Salto, 14R, IT - 16146 Genova (GE) Via Statale 12, 56/58, IT - 41036 Medolla (MO)

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

Provision of a global service for the management of medical devices. Design, production and trade of single use medical devices for surgical, interventional an diagnostic area. Placing on the market under own brand of electromedical systems for tumoral ablation.

Through an Audit, Report No. 28110400 004, 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 1531509.

This Certificate is valid from 2018-09-25 to 2020-03-30.

The reference date for all the next audits is (day-month): 21-03.

Milan, 2018-09-25. First Certification: 2014-03-31

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 the Directives 93/42/EEC. 90/385/EEC or 98/79/EC have been fulfille



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



