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:

Design and delivery of the management service of medical supplies in a global service regime. Manufacturing and placing on the market of disposable devices for the surgical, diagnostic and interventional fields. Manufacturing and placing on the market of electrode needles for radiofrequency thermoablation. Trade of the disposable for the surgical, diagnostic and interventional fields.

Through an Audit, Report No. 7983845010MT28, proof has been furnished that the quality management system fulfils the requirements of the standard

UNI CEI EN ISO 13485:2021

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

Certificate Registration No. 39 05 1531509.

This Certificate is valid from 2023-04-28 to 2026-04-27

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

Milan, 28/04/2023. First Certification: 2020-07-13

The Certification responsible: Cesare Gentile

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, 98/79/EC or Regulations (UE) 2017/745, (UE) 2017/746 have been fulfilled



SGQ Nº 083A SGA Nº 052D

Membro deali Accordi di Mutuo Riconoscimento EA, IAF e ILAC

Signatory of EA, IAF and ILAC Mutual Recognition Agreement



Management System EN ISO 13485:2016



