UNI CEI EN ISO 13485:2012

EC DECLARATION OF CONFORMITY

The undersigned Giuseppe Lodola, as the legal representative of the Medical Due Srl, with headquarters in Via Trento, No. 43 - IT-37014 - Castelnuovo del Garda (VR) Italy , VAT number IT02895150239

DECLARES

under his own personal responsability that the ENDOLOG medical devices (intramedullary titanium alloy nails and screws), with the following production references:

Ref	Description	Class
1500-044	Endolog (Endolog titanium nail Ø 4,5 x 40 mm)	IIb
1500-045	Endolog (Endolog titanium nail Ø 4,5 x 45 mm)	IIb
1500-046	Endolog (Endolog titanium nail Ø 4,5 x 46,9 mm)	IIb
1500-415	Endolog (Endolog titanium screw Ø 3,66 mm - L. 15 mm)	IIb
1500-417	Endolog (Endolog titanium screw Ø 3,66 mm - L. 17 mm)	IIb
1500-420	Endolog (Endolog titanium screw Ø 3,66 mm - L. 20 mm)	IIb
1500-425	Endolog (Endolog titanium screw Ø 3,66 mm - L. 25 mm)	IIb

• meet the provisions of Directive 93/42/EEC implemented in Italy by Legislative Decree No 46 of 24/02/1997 and subsequent amendments supplementary (eg 47/2007/CE Directive transposed by Legislative Decree No 37 of 25/01/2010) and in particular the essential requirements of Annex I.

• are considered belonging to the class IIb, Rule 8 of Annex IX to that Directive 93/42/EEC as amended supplementary.

• are monitored at every stage of production as determined by the Company Management System according to UNI CEI EN ISO 13485:2012 "Medical devices - Quality management systems - Requirements for regulatory purposes ".

In addition, the manufacturer must undertake to preserve and make available to the Certifying Organization and Competent Authority throughout the product documentation (technical file and production records) for a minimum period of 15 years since the last date of product manufacturing.

Medical Due S.r.l.
Giuseppe Lodola

Castelnuovo del Garda (VR) Italy, 19/05/2017