

Rotating Support for Laparoscopy Side To Side Evolution (sTs Evo)

Temporary Non-Invasive Medical Device Class I

CE DECLARATION OF CONFORMITY

THE UNDERSIGNED Antonio Ferraro, LEGAL REPRESENTATIVE OF THE COMPANY

Unlimited Technology - Centro direzionale Isola G2 – 80143 Napoli (NA) - Italy

DECLARES THAT THE FOLLOWING MEDICAL DEVICE DISTRIBUTED BY THIS COMPANY:

Class	I
Function	Temporary non-invasive medical device for laparoscopic operations on animals.
Name	Rotating Support.
Model	sTs Evo.
Serial Number	

IS IN CONFORMITY WITH THE PROVISIONS OF THE DIRECTIVES

"MACHINERY" (2006/42/EC and subsequent amendments)

"MEDICAL DEVICES" (2007/47/EC and subsequent amendments)

"ELECTROMAGNETIC COMPATIBILITY" (2004/108/EC and subsequent amendments)

AND WITH THE NATIONAL IMPLEMENTING PROVISIONS

D.Lgs 17/2010; D.lgs 37/2010; D.Lgs 194/2007

IS IN CONFORMITY WITH THE PROVISIONS OF THE FOLLOWING HARMONIZED STANDARDS:

UNI EN 60601-1: Electromedical equipment Part 1: General requirements for basic safety and essential performance

CEI EN 61557-8 1998-09 "Electrical safety in low-voltage distribution systems up to 1 kV AC and 1.5 kV DC - Equipment for testing, measuring or monitoring the protection systems Part 8: Equipment for insulation monitoring in IT systems"

CEI EN 61558-2-15 2001-10 "Safety of transformers for medical use"

CEI EN 60335-1: Safety of household and similar electrical appliances

UNI EN 292-1/-2/-2:A1 Safety of machinery. Basic concepts, general principles of design.

UNI EN 294 Safety of machinery. Safety distances to prevent hazard zones being reached by upper limbs.

UNI EN 953 Safety of machinery - Guards - General requirements for the design and construction of fixed and movable guards

CEI EN 61340-5-1:2008 Protection of electronic devices from electrostatic phenomena - general requirements.

EN 50081-1 Electromagnetic compatibility: emissions

EN 50082-1 Electromagnetic compatibility: immunity

