

20. Dichiarazione di conformità



declares under its complete responsibility that the product

MEDICAL DEVICE

with particular reference

Product name	<i>Osteo Warm</i>
Type	<i>Radiofrequency</i>
Serial number	<i>170612/2</i>
PLC number	<i>17-000103</i>
Date	<i>12 GIUGNO 2017</i>
Electrical safety class	<i>II BF</i>

Is in conformity with DIRECTIVE 93/42/ECC as amended by DIRECTIVE 2007/47/CE
(Medical Devices) Class IIA



Bureau Veritas Italia spa

and that the standard referenced below have been applied

EN 60601-1:2007	Medical Electrical Equipment- Safety requirement for electrical systems
EN 60601-1-2:2010	Medical Electrical Equipment- Electromagnetic compatibility – Requirements and tests
EN 60601-1-6:2010	General requirements for basic safety and essential performance - Collateral standard: Usability
EN 62366:2008	Medical devices - Application of usability engineering to medical devices
EN 62304:2006	Medical device software - Software life-cycle processes
CEI UNI EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2012	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
ISO 10993-1:2009	Biological evaluation of medical devices - Evaluation and testing within a risk management process

MED ELETTRONICA
(Quality Manager)

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