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## **DECLARATION OF CONFORMITY**

### Medical Devices

We, the undersigned, declare that to the best of our knowledge that the products listed below meets the intent of the Medical Devices Directive 93/42/EEC.

Product name/Model number	Class	GMDN Code
870 A	I	36679
870 S	I	36679
870 C	I	36679

(Detailed variants on next page)

In addition we ensure and declare that the above listed products falling within Class I, according the annex IX of the MDD Directive, are conform to the EN 60601-1:2006/AC:2010 and EN 60601-1-2:2007/AC:2010 and respect all the requirements of the applicable standards

Applied standards;

- EN 60601-1:2006/A1:2013 General requirements for basic safety and essential performance
- EN 60601-1-2:2007/AC2010 Electromagnetic compatibility
- EN ISO14971:2012 Application of risk management to medical devices
- EN ISO1041:2008 Information supplied by the manufacturer of medical devices
- EN 980 Symbols for use in the labelling of medical devices
- EN 62304:2006/AC:2008 Medical device software - Software life-cycle processes
- EN 60601-1-6 :2010 Usability
- EN ISO 10993 :2009/AC :2010 Biocompatibility

All required documentation is kept up to date and available to competent authorities.

This Declaration of Conformity covers Medisoft Treadmill's products manufactured on our production site;

*Via Germania, 14  
35127 Camin (PD)  
ITALY*

Sorinnes, 15 July 2016

Function: Quality Manager

Name: Eric Dion

Signature:



Optional variants:

Name	Ref. :
PC color console 7" with touch screen	MSIT-00-06
Auto stop switch – safety lanyard	MSIT-00-07
Patient support with brackets structure, hooks for slings, adjustable height (support weight over 200Kg.)	MSIT-00-08
Harness patient support groin [ <b>must be used with MSIT-00-08</b> ]	MSIT-00-09
Patient safety support jacket [ <b>must be used with MSIT-00-08</b> ]	
M size	MSIT-00-10
L size	MSIT-00-11
XL size	MSIT-00-12
XXL size	MSIT-00-13
Arm pit support	MSIT-00-14
Elbow support	MSIT-00-15
Removable support chair	MSIT-00-16

Name: Eric Dion

Signature:


