

DECLARATION OF CONFORMITY

Medical Devices

We, the undersigned, declare that the products listed below meets the intent of the Medical Devices Regulation (EU) 2017/745.

Product name/Model number	Reference	Class	GMDN Code
870 A	MSIT-00-01	I	36679
870 S	MSIT-00-02	I	36679
870 C	MSIT-00-03	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 VIII of the MDR Regulation, are conform to the EN 60601-1:2006/A1:2013 and EN 60601-1-2 :2015 and respect all the requirements of the applicable standards.

These products comply with the below mentioned directives regarding the Restriction Of the use of certain Hazardous Substances in electrical and electronic equipment.

- Directive 2002/95/EC of the European Parliament and of the Council ("RoHS 1")
- Directive 2011/65/EU of the European Parliament and of the Council ("RoHS 2"); and
- Commission Delegated Directive (EU) 2015/863

Applied standards;

- EN 60601-1:2006/A1:2013 General requirements for basic safety and essential performance
- EN 60601-1-2 :2015 Electromagnetic compatibility
- EN ISO14971:2012 Application of risk management to medical devices
- EN ISO1041:2008 Information supplied by the manufacturer of medical devices
- EN ISO 15223-1:2016 Symbols to be used with medical device labels
- 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.

(See page 2 for accessories and options covered by this declaration)

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

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Function: Quality Manager
Name: Eric Dion
Signature:

Annex I

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 [must be used with MSIT-00-08]	MSIT-00-09
Patient safety support jacket [must be used with MSIT-00-08]	
S Size	MSIT-00-18
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

Function: Quality Manager

Name: Eric Dion

Signature: