



















November 22, 2023

Ref: MR Conditional Status on Salter Labs InfuseIT Pressure Infusors

Non-clinical testing demonstrated that these devices (Appendix 1) are MR Conditional. These devices can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 7-Tesla or less.
- Maximum spatial gradient magnetic field of 1,900-Gauss/cm (19-T/m).

These devices should be positioned away from the area being scanned to reduce the possibility of artifacts on the image.

 30 Spur Drive El Paso, TX 79906 USA Made in China www.Sun-Med.com	  MedEnvoy Switzerland Gotthardstrasse 28 6302 Zug Switzerland	 	 	 
 MT Promedt Consulting GmbH Ernst-Heckel-Straße 7 66386 St. Ingbert Germany	 MT Promedt Consulting Ltd. Beaver House, 23-38 Hythe Bridge Street Oxford, OX1 2EP United Kingdom		 -20°C STORAGE TEMP	 10°C OPERATING TEMP
 MedEnvoy NL-IM-00000248 Prinses Margrietplantsoen 33 Suite 123 2595 AM, The Hague The Netherlands	 MedEnvoy UK Limited 85, Great Portland Street – First Floor London, W1W 7LT United Kingdom		Non-clinical testing demonstrated that these devices are MR Conditional. These devices can be scanned safely in an MR system under the following conditions: • Static magnetic field of 7-Tesla or less. • Maximum spatial gradient magnetic field of 1,900-Gauss/cm (19-T/m). These devices should be positioned away from the area being scanned to reduce the possibility of artifacts on the image.	
		 LV05008 REV BB 2023/05		

The information regarding MR conditional claims are evidenced on both the label and technical documentation.

Sincerely,



Daniel Kornowicz

International Regulatory Director



Appendix 1

Disposable	DESCRIPTION	PRODUCT NUMBER
	InfuseIT 500 mL with stopcock valve	ZIT-500-1 (individual device) ZIT-500-X (indicates number of individual units in a case)
	InfuseIT 500 mL with thumbwheel valve	ZIT-502-1 (individual device) ZIT-502-X (indicates number of individual units in a case)
	InfuseIT 1000 mL with stopcock valve	ZIT-1000-1 (individual device) ZIT-1000-X (indicates number of individual units in a case)
	InfuseIT 1000 ml with Thumbwheel Valve	ZIT-1002-1 (individual device) ZIT-1002-X (indicates number of individual units in a case)
	InfuseIT 3000 mL with stopcock valve	ZIT-3000-1 (individual device) ZIT-3000-X (indicates number of individual units in a case)
	InfuseIT 3000 mL with thumbwheel valve	ZIT-3002-1 (individual device) ZIT-3002-X (indicates number of individual units in a case)
Reusable	DESCRIPTION	PRODUCT NUMBER
	InfuseIT 500 mL with stopcock valve	ZIT-520-1 (individual device) ZIT-520-X (indicates number of individual units in a case)
	InfuseIT 1000 mL with stopcock valve	ZIT-1020-1 (individual device) ZIT-1020-X (indicates number of individual units in a case)