

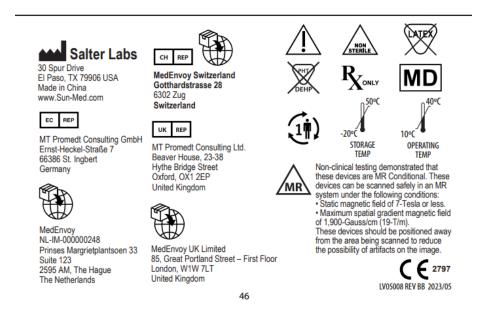
November 22, 2023

## 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.



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	ZIT-3002-1 (individual device)
valve	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)