

Technical Bulletin

Ref: **TB-23002-ENG**

Issue date: August 2023

Product: INOmax DS_{IR}[®], INOmax DS_{IR}[®] Plus, INOmax DS_{IR}[®] Plus MRI,
INOflo DS, INOvent, Investigational Blinded NO Delivery System,
Investigational NO Delivery System for Human Use Only,
Investigational NO Delivery System for Animal Use Only.

Priority: Low

Affected parts: Accessories

Classification: Information for Distribution

Subject: Chinese Regulatory Labelling Additions

The purpose of this Technical Bulletin is to inform the user of additional labeling being introduced to the accessories listed in the table below.

The following part numbers will have an additional Chinese regulatory label that is required for import into the country. The information contained in the label is pertinent to China only.

Here are digital and photographic examples of the regulatory label being added to the accessory polybag packaging.

<p>产品名称: 产品型号/规格: 序列号: 生产日期: 失效日期: 注册证编号: 20233080216</p> <p>其他内容详见说明书</p>



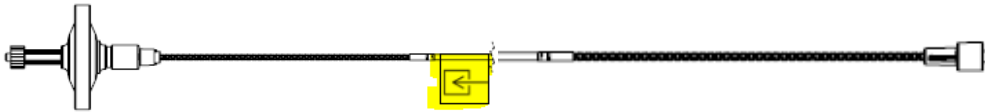
The information called out on the Chinese labeling above is:

- Product name
- Model No./Specification
- Serial/Lot No.
- Production Date
- Expiration Date
- Registration No.
- "See the manual for other contents"

IMPORTANT: Please continue to use your existing inventory of accessories until exhausted. The accessories in inventory are unaffected by this change as the change is for labeling only and does not affect fit/form/function of the accessory products.

Note: Not all accessories listed below may be required in all regions.

In addition, for P/N 50404 Patient Gas Sample Line with Filter (5-pk), there is a label flag being added to the sample line as shown below. P/N 50404 is the only accessory pack affected by this change.



50404 Patient Gas Sample Line with Filter with added label flag on sample line

Affected accessories (5 pack)

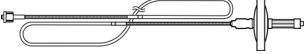
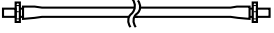
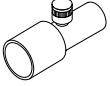

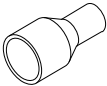


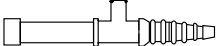





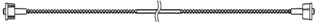
Image	Description	Pack of Five (Part Number)
	Patient Gas Sample Line with Filter	50404
	NO/N ₂ Injector Tube	50407
	Adapter, Gas Sample Tee	50408
	Adapter, 22M/15F X 22M/15F	50409

Image	Description	Pack of Five (Part Number)
	Adapter, 22F X 15M	50410
	Adapter, 15M Fits 4.5mm ID Tubing	50411
	One-Way Valve, 22F X 22M	50412
	Sample Tee, O ₂ Tubing	50413
	Water Separator Cartridge, INOmax DS _{IR}	50414
	Adapter, 90 Degree Sample Port	50419
	Adapter, Cuff, 22mm ID X 22mm ID	50420
	Pediatric Extension, 15 mm, 6 inches	50421
	Neonatal Tubing, 10mm (2 pieces)	50422
	Patient Gas Sample Line with (Nafion)	50424

For technical assistance regarding any of the above devices, please contact Product Support at 1-877-566-9466 (North America) or your specific country manager.

Mallinckrodt Manufacturing LLC
6603 Femrite Drive,
Madison, WI 53718-6801 USA

Mallinckrodt, the “M” brand mark and the Mallinckrodt Pharmaceuticals logo are trademark of a Mallinckrodt company. Other brands are trademarks of a Mallinckrodt company or their respective owner. ©2023 Mallinckrodt.



Europe

European Authorized Representative
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

