



09 September 2016

Mr Jim Quackenbush  
Medspira  
2718 Summer Street NE  
Minneapolis  
MN 55413  
USA

**RE: Anorectal Manometry System (mcompass) GMDN Code:  
35053, 17781**

Dear Mr Quackenbush

Further to your recent significant change notification, I am happy to inform you that Product Family, **Anorectal Manometry System (mcompass)** file number **252.858** has been amended as follows:

to add the new biofeedback therapy (**Model: RMD-002**), 2-channel catheter (**Model: RMD-002-004**), and 5\_channel catheter (**Model: RMD-002-003**) to the current version of the mcompass™ Anorectal Manometry System diagnostic (Model: RMD-001) under GMDN 35053 (gastrointestinal motility analysis system) and GMDN 17781 (rectosphincteric balloon) product families.

Approval conditions: None

Our reference for this amendment is **252.858.03**. This amendment takes effect from **31 Aug 2016**.

The NSAI Notified Body number, 0050, may be used on the additional model(s) / trade name(s) above, in conjunction with the CE Marking of conformance.

Yours Sincerely

A handwritten signature in black ink that reads "Susan Murphy".

Susan Murphy  
European Medical Device Operations Manager  
Medical Devices  
NSAI

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