Declaration of Conformity

Manufacturer:
Medspira, LLC
2718 Summer Street NE
Minneapolis, MN 55413 USA

Authorized Representative:
CEpartner4U BV
Esdoornlaan 13
3951 DB Maarn
The Netherlands

Device Name: mcompass™ Anorectal Manometry System

mcompass™ Biofeedback Anorectal Manometry System

Covered Models: RMD-001 and RMD-002

Conformity:
The devices listed above conform to the requirements stated in the documents below.

Doc #	Title	Edition/Date
93/42/EEC	Medical Device Directive	2007

Device Class: I - Measuring

Conformity Assessment Route: Annex II Full Quality Assurance System

Notified Body:
National Standards Authority of Ireland (NSAI) - Registration number: CE 0050
1 Swift Square, Northwood , Santry
Dublin 9
Ireland

MDD Certificate: 252.858

QMS Certificate: MD19.4639 and CM19.4639

Supporting Documentation: Summary Technical Document (DOCU5006 Revision 007)

I attest that each device that is subject to this declaration complies with the applicable Essential Requirements of the Medical Device Directive (93/42/EEC, as amended in 2007) and has met all the applicable conformity assessment elements as evidenced by the certifications listed herein.

Name & Title: Jim Quackenbush, CEO, Medspira LLC

Signature: _____ Date: 12 DEC '18