VISTA MEDICAL Ltd.

Unit #3 - 55 Henlow Bay
Winnipeg MB. Canada R3Y1G4
Phone 204 949-7676 800 563-7676
FAX 204 949-7650 800 664-2044

Document	Version	Date	Author	Authorization
QA021	V2.8	15 May 2020	Ted Duthoit	Shawn Tester

Declaration of Conformity

1. This declaration is issued under the sole responsibility of the manufacturer.

2. The medical device for which this declaration is issued is a pressure sensing array made of flexible fabric that shows interface pressures between a subject and the supporting surface. The family of models vary in size and shape, but all have the same internal technology.

3. Vista Medical Limited is the manufacturer of these medical devices which have the trade name of BodiTrak or FSA Pressure Mapping. The manufacturing plant and the office headquarters are both located at the following address:

   Unit 3, 55 Henlow Bay
   Winnipeg, Manitoba, Canada,
   R3Y 1G4

4. Our European Authorized Representative is Emergo by UL:

Headquarters	European Office
2500 Bee Cave Road Building 1, Suite 300 Austin Texas 78746 Tel: +1-512-222-0262	Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands Tel: (31) (0) 70 345-8570

5. The products listed below are non-invasive, active medical devices. The risk class for this family of medical devices is Class 1M, as per the European Medical Device Directive 93/42/EEC, Annex VI.

6. Vista Medical hereby declares our Product Quality Assurance System conforms with the relevant provisions of the Swedish national legislation LVFS 2003:11, transposing Annex VI of the European Community Medical Device Directive 93/42/EEC in the manufacture of the products listed below.

7. Vista Medical's products have been certified for CE marking by Intertek Semko, Notified Body 0413 of Sweden, through conformity to the international standard ISO 13485:2016 for a Quality Management System.

8. Vista Medical Ltd. also hereby declares our product to conform to the following international standards through certification by TUV SUD America Inc.:

   UL 60601-1:2014 – Medical Device Basic Safety and Essential Performance
   IEC 60601-1-2:2014 (Ed 4.0) – Medical Device Electromagnetic Compatibility

Products

The following is a list of Vista Medical's products by model designation.

- For the trade name FSA Pressure Mapping the model numbers are:

  UT1009, UT1010, UT1021, UT1025, UT1026, UT1027, UT3010, UT3020, UT4010, UT5010, UT5010S, UT6010, FT1005, FT1015, FT1020, FT1030, FT1035, CP1000, ST1500, ST1526, ST3510

  Interface Module: Type 4, Type 5, Type 5E

- For the trade name BodiTrak the model numbers are:

  BTxxxx, where xxxx are numerals from 1000 to 9999

  BT2-xxyy-zzz, where xx and yy are numerals from 01 to 64 and zzz are numerals from 000 to 999

Declaration signed on _____May 15, 2020_____ in Winnipeg, Mb, Ca

_____
General Manager – Shawn Tester

Document Revision History

Version	Date	Change
v10 r3	19 Sep 2012	-existing version
v10 r4	8 Aug 2013	-Rule 1 added for classification justification -declaration statement reworded as per EC certificate -product list updated per Intertek product list from 2 Oct 2012
v10 r5	1 May 2014	-product list updated per Intertek product list from 25 Apr 2014
v10 r6	5 Aug 2014	-device classification changed to active device -route to conformity now Rule 12 instead of Rule 1 -trade name of product clarified
V2.7	5 Jun 2018	-added conformity to electrical standards -new address for EC Authorized Rep
V2.8	15 May 2020	-updated to ISO 13485:2016 and the revised MDD product list