ZERTIFIKAT • CERTIFICATE • 認證證書 • СЕРТИФИКАТ • CERTIFICADO • CERTIFICAT

America

CERTIFICATE

No. U8V 16 10 71797 005

Holder of Certificate: **Vista Medical Ltd.**
Unit #3-55 Henlow Bay
Winnipeg MB R3Y 1G4
CANADA

Certification Mark:

C US

Product: **General Medical Devices**
Pressure Mapping System

The product was voluntarily tested according to the relevant safety requirements noted above. It can be marked with the certification mark above. The mark must not be altered in anyway. This product certification system operated by TÜV SÜD America Inc. most closely resembles system 3 as defined in ISO/IEC 17067. Certification is based on the TÜV SÜD "Testing and Certification Regulations". TÜV SÜD America Inc. is an OSHA recognized NRTL and a Standards Council of Canada accredited certification body.

628348

Test report no.: 240-1202474-101/7169001637

Date, 2016-10-14

America

CERTIFICATE
No. U8V 16 10 71797 005

Model(s):

BT1505, BT1510, BT1526, BT3510, BT3530, BT3520, BT3526, BT4510, BT4526, BT5010, BT5510, BT5526, BT6510, BT6511, BT6526, BT7510, BT7515, BT7520
See attachment for License Conditions

Parameters:

Rated Input Voltage:	5Vdc
Rated Input Current:	250mA
Protection Class:	II
Degree of Protection:	Type B applied part

Tested according to:

CAN/CSA-C22.2 No. 601.1-M90, excluding:
EMC (clauses 6.8.2 and 36),
Biocompatibility (clause 48), and
Programmable Electronic Systems (clause 52.1)
CAN/CSA-C22.2 No. 60601-1:2008-02, excluding:
Usability (clauses 7.1.1 and 12.2),
EMC (clauses 7.9.2.2 and 17),
Biocompatibility (clause 11.7) and
Programmable Electrical Medical Systems (clause 14)
UL 60601-1:2003, excluding:
EMC (clauses 6.8.2 and 36),
Biocompatibility (clause 48) and
Programmable Electronic Systems (clause 52.1)
ANSI/AAMI ES 60601-1:2005/A2:2010, excluding:
Usability (clauses 7.1.1 and 12.2),
EMC (clauses 7.9.2.2 and 17),
Biocompatibility (clause 11.7) and
Programmable Electrical Medical Systems (clause 14)
Note: The use of the TÜV SÜD NRTL Mark does not infer the acceptability of ANSI/AAMI ES 60601-1:2005/A2:2010 by OSHA

Production Facility(ies):

71797

Attachment for Certificate no. U8V 16 10 71797 005
Dated 2016-10-14

America

Company: **Vista Medical Ltd.**
Unit #3-55 Henlow Bay
Winnipeg, MB R3Y 1G4
Canada

License Conditions:

1. The equipment has not been investigated for the protection against hazards of explosions in medically used rooms.
2. Instructions and equipment marking related to safety shall be in a language acceptable in the country in which the equipment is to be installed.
3. Equipment to be evaluated to Excludes Usability (clauses 7.1.1, and 12.2), Biocompatibility (clause 11.7), Programmable Electrical Medical Systems (clause 14), Electromagnetic Compatibility (clauses 7.9.2.2 and 17)
4. Accessories, attachments, and attached equipment other than those noted in the report have not been investigated. If provided, such parts shall be of an acceptable type suitable for use and the resulting combination shall be investigated under IEC 60601-1:2005 and applicable national requirements, and as a ME System (clause 16) if applicable.
5. Unit shall be powered via a certified computer compliant with IEC 60950-1 or IEC 60601-1, and applicable national requirements.
6. Secondary circuits within device considered as Overvoltage Category I per IEC 60664-1. Unit shall be powered by a computer investigated for Overvoltage Category II or better.