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

America

C E R T I F I C A T E

No. U8 001092 0001 Rev. 01

Holder of Certificate: **Adaptive Sensory Technology Inc.**
9823 Pacific Heights Blvd Suite CD
San Diego CA 92121
USA

Certification Mark:

C US

Product: **General Medical Devices**
Manifold Contrast Vision Meter

This product was voluntarily tested to the relevant safety requirements referenced on this certificate. It can be marked with the certification mark above. The mark must not be altered in any way. 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.

Test report no.: 095-72129011-100

Date, 2020-09-24

(Antony Young-Taylor)

TÜV SÜD America Inc. • 10 Centennial Drive • Peabody • MA 01960 • USA

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America

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No. U8 001092 0001 Rev. 01

Model(s): **Cart-based main unit: 001.001.001 with Remote Control: 001.002.001**

Brand Name: **Adaptive Sensory Technology**

Brand:

Adaptive Sensory Technology

Tested according to:

ANSI/AAMI ES60601-1:2005/(R)2012
CAN/CSA C22.2 No. 60601-1:2014

Production Facility(ies):

001092

Parameters:

Rated Input:	Main unit: 120 VAC, 60 Hz, 92 VA Remote control: 9 VDC, 2.77 A External power supply/charger to phone remote control (Samsung): Input: 100-240 VAC, 50-60 Hz, 0.7 A Output: 5 VDC, 3.0 A or 9 VDC, 2.77 A
Protection Class	Class I (main unit) Class II (remote control with external power supply/charger)
Operating Ambient:	10°C to 35°C 20-75% Rh, non-condensing
Elevation for use:	0-2000 m above sea level

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Additional information:

Exclusion:

Clause 11.7 Biocompatibility, referencing ISO 10993

Clause 17 EMC, referencing IEC 60601-1-2

The product is also evaluated according the following standards:

IEC 60601-1-6:2010/AMD1:2013
IEC 62368-1:2015
All applicable clauses of IEC 62366-1:2015 associated with usability of Medical electrical equipment have been addressed.

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