

Certification Record

Listing#: E114977

Report #: 102560/102560A

Original Certification Date: April 8, 2020

Revised Certification Date:

This Certification is issued to: Endoluxe, Inc. 5337 Happy Hollow Road Dunwoody, GA 30360-1233 USA

Stating that the product(s): Vision System Receiver & Charger, Model Numbers 1057 (Charger) & 1058 (Receiver)

Orb, Model Number 1056

Achieved Certification to the following standard(s): UL 62368-1:2014/CSA C22.2 No. 62368-1-14 (2nd Edition) Audio/video, information and communication technology equipment – Part 1: Safety requirements

AAMI ES 60601-1:2005/(R)2012 +A1:2012 and CSA C22.2 No. 60601-1:14, Medical electrical equipment, Part 1: General requirements for basic safety and essential performance; IEC 60601-1-6:2010 +A1:2013, Medical electrical equipment Part 1-6 General requirements for safety - Collateral Standard: Usability

Harold Raab

Sr. Project Engineer,

Harold Rent

Eurofins MET Labs Safety Laboratory



All changes proposed in the previously identified product that affects the above information must be submitted to Eurofins MET Labs for evaluation prior to implementation to assure continued MET Certification status.

The covered product(s) shall be subject to follow-up inspections to ensure that the Certified product(s) are identical to the product sample evaluated by Eurofins MET Labs and that all manufacturer's responsibilities are being fulfilled as specified in the Manufacturer's Responsibility section of the Certification report. The applicant named above has been authorized by Eurofins MET Labs to represent the product(s) listed in this record as "MET Certified" and to mark this/these product(s) according to the terms and conditions of the MET Applicant Contract, MET Listing Reports, and the applicable marking agreements. Only the product(s) bearing the MET Mark and under a follow-up service are considered to be included in the MET Certification program. This certification has been granted under a System 3 program as defined in ISO/IEC 17067.



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