CSA Group

Certificate of Compliance

Certificate: 70014584 **Master Contract:** 262336

Project: 70116057 **Date Issued:** 2017-02-10

Issued to: **Eurorad S.A.**
2 Rue Ettore Bugatti
Eckbolsheim, 67201
FRANCE

The products listed below are eligible to bear the CSA Mark shown with adjacent indicators 'C' and 'US' for Canada and US or with adjacent indicator 'US' for US only or without either indicator for Canada only.

C US

Issued by: *Jean-Philippe Laplante*
Jean-Philippe Laplante

PRODUCTS

CLASS - C878001 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS
CLASS - C878081 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS-Certified to US Standards

Gamma detection device for radio guided surgery, models: Europrobe 3.2, detachable cord, portable, rated: 100-230Vac, 50/60Hz, 200-120mA. 3.6Vdc by LiSOCl2 battery for Bluetooth probe SOE3216-BT

1. Type of protection against electric shock: Class I
2. Degree of protection against electric shock: Type BF
3. Degree of protection against ingress of water: IPX0
4. Method of Sterilization: None
5. Suitability for use in an Oxygen Rich Environment: Medical device not intended to be used in an Oxygen Rich Environment
6. Suitability to use Medical device in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide: Medical device not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
7. Mode of operation: Continuous
8. Environmental Conditions: Normal: 10-40°C, 30- 75% RH, 700-1060hPa

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APPLICABLE REQUIREMENTS

CSA Standards:

CAN/CSA-C22.2 No. 60601-1:14	CAN/CSA-C22.2 No. 60601-1:14: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (Adopted IEC 60601-1:2005 edition 3.0 + AMENDEMENT 1, 2012-07, MOD)
CAN/CSA C22.2 No.60601-1-6:11	Medical Electrical Equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability (Adopted IEC60601-1-6:2010 + A1:2013)

ANSI/AAMI Standards:

ANSI/AAMI ES60601-1:2005/(R)2012, AND C1:2009 AND A2:2010(R)2012 (Consolidated text - edition 3.1)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005+A1:2012, MOD).

Subject to the following qualifications:

(1) The main supply cord set provided with the Medical Electrical Equipment or the Medical Electrical System must be a North American Certified power supply cord set as indicated in the CSA description report.

(2) A Medical Electrical Equipment or Medical Electrical System which is not provided with a North American Certified power supply cord set is certified as a component or a sub-assembly.

(3) The user replaceable mains (line) fuse must be an approved type acceptable to the authorities where the equipment is sold.

(4) Evaluated to CAN/CSA-C22.2 No. 60601-1:14 and ANSI/AAMI ES60601-1:2005/(R)2012, AND C1:2009 AND A2:2010(R)2012 (Consolidated text - edition 3.1) excluding (Not Evaluated) requirements for Electromagnetic compatibility (Clause 17) and Biocompatibility (Clause 11.7)

(5) SAFETY HAZARDS resulting from the intended physiological function of EQUIPMENT covered by this Standard are not considered.

(6) Interconnection of this medical device with other medical devices, medical used systems or non medical devices shall be evaluated to the requirements of Clause 16 in the end use application.

(7) Safety Risk Management: A risk management process complying with the requirements of standard ISO 14971 was inspected during the evaluation of this medical device and/or additional considerations were taken into account since the subject legacy medical device was evaluated to the previous edition of this standard. During the evaluation of this medical device, the risk management decisions affecting the test requirements have been taken into consideration. Changes/Updates in risk management documents that affect the safety of this medical device during its lifecycle shall be communicated to the CSA Group as a condition for continued certification.

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Supplement to Certificate of Compliance

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The products listed, including the latest revision described below, are eligible to be marked in accordance with the referenced Certificate.

Product Certification History

Project	Date	Description
70116057	2017-02-10	CSA c/us report update for an alternate construction (PS), correction of some mistakes in the CCL and transition from 60601-1 3.0 to 3.1 edition on a GAMMA DETECTION DEVICE FOR RADIO GUIDED surgery, model: Europrobe 3.2
70014584	2016-03-09	CSA c/us certification of a Gamma detection device for radio guided surgery, model: Europrobe 3.2