



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

HITACHI, LTD. MEDICAL SYSTEM OPERATIONS GROUP,  
KASHIWA EMC CENTER  
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ELECTRICAL (EMC)

Valid To: October 31, 2019

Certificate Number: 2614.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following electromagnetic compatibility tests on medical electrical equipment:

**Tests:**

**Emissions**

Radiated and Conducted

Current Harmonics

Voltage Fluctuations and Flicker

**Immunity**

Electrostatic Discharge (ESD)

Radiated Immunity

Electrical Fast Transient/Burst

Surge Immunity

Conducted Immunity

Power Frequency Magnetic Field Immunity

Voltage Dips, Short Interruptions

**Test Methods<sup>1</sup>:**

CISPR 11; EN 55011 (*Radiated emissions up to 1 GHz*)

EN 61000-3-2; IEC 61000-3-2; JIS C 61000-3-2

EN 61000-3-3; IEC 61000-3-3

EN 61000-4-2; IEC 61000-4-2; JIS C 61000-4-2

EN 61000-4-3; IEC 61000-4-3; JIS C 61000-4-3  
(*Testing up to 2.7 GHz, 28 V/m  
and from 2.7 to 6.0 GHz, 9 V/m*)

EN 61000-4-4; IEC 61000-4-4; JIS C 61000-4-4

EN 61000-4-5; IEC 61000-4-5; JIS C 61000-4-5  
(*excluding coupling to interconnection lines  
and ITU-T K series surge testing*)

EN 61000-4-6; IEC 61000-4-6; JIS C 61000-4-6

EN 61000-4-8; IEC 61000-4-8; JIS C 61000-4-8

EN 61000-4-11; IEC 61000-4-11; JIS C 61000-4-11

**Tests:**

*Generic and Product Specific EMC Standards*  
Medical Devices

**Test Methods<sup>1</sup>:**

EN 60601-1-2, Ed. 2, 3, and 4;  
IEC 60601-1-2, Ed. 2, 3, and 4;  
EN 60601-2-37; IEC 60601-2-37;  
JIS T 0601-2-37 (*EMC section only*)

**On the following products or types of products:**

Industrial, Scientific, Medical (ISM)

<sup>1</sup>When the date, revision or edition of a test method standard is not identified on the scope of accreditation, the laboratory is expected to be competent in the use of the current version within one year of the date of publication, per part C., Section 1 of A2LA R101 - *General Requirements- Accreditation of ISO-IEC 17025 Laboratories*.

WITHDRAWN





## *Accredited Laboratory*

A2LA has accredited

# **HITACHI, LTD. MEDICAL SYSTEM OPERATIONS GROUP, KASHIWA EMC CENTER**

*Kashiwa-Shi, Japan*

for technical competence in the field of

## **Electrical Testing**

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories*. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer to joint ISO-ILAC-IAF Communiqué dated 8 January 2009).



Presented this 6<sup>th</sup> day of September 2017.

A handwritten signature in black ink, appearing to be 'L. Sen', written over a horizontal line.

President and CEO  
For the Accreditation Council  
Certificate Number 2614.01  
Valid to October 31, 2019

*For the tests to which this accreditation applies, please refer to the laboratory's Electrical Scope of Accreditation.*