

# Scope of Accreditation

(Measurement Method)

Accreditation Number : VLAC-001-6

Expiration Date : March 30, 2022

[Name of Laboratory]

Japan Quality Assurance Organization

[Test site name]

Kitakansai Testing Center, Medical Devices Testing Div.

[Test site Address]

1-7-7, Ishimaru, Minoh-shi, Osaka 562-0027, Japan

[Measurement Method]

Tests for medical electrical equipment based on products safety standards

IEC 60601-1 series	IEC 60601-2 series	IEC 80601-2 series	IEC 62304
IEC 62366 series	EN 60601-1 series	EN 60601-2 series	EN 80601-2 series
EN 62304	EN 62366 series		
JIS T 0601-1 series	JIS T 0601-2 series	JIS T 1115	JIS T 2304
JIS T 62366 series	JIS T 5602* <sup>1</sup>	JIS T 5701* <sup>1</sup>	JIS T 80601-2 series* <sup>1</sup>
JIS T 1140* <sup>1</sup>	JIS T 7209* <sup>1</sup>		
ISO 6875* <sup>1</sup>	ISO 7494-1* <sup>1</sup>	ISO 80601-2 series* <sup>1</sup>	ISO 8359* <sup>1</sup>

\*<sup>1</sup>: Added as of May 25, 2021

**Voluntary EMC Laboratory Accreditation Center Inc.**

# Scope of Accreditation

(Test standards)

**Accreditation Number : VLAC-001-6**

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[Name of Laboratory]

**Japan Quality Assurance Organization.**

[Test site name]

**Kitakansai Testing Center, Medical Devices Testing Div.**

[Test site Address]

**1-7-7, Ishimaru, Minoh-shi, Osaka 562-0027, Japan**

[Test standards]

**Tests for medical electrical equipment based on products safety standards**

IEC 60601-1:2005	EN 60601-1:2006	JIS T 0601-1:2012
IEC 60601-1:2005+A1:2012	EN 60601-1:2006+A12:2014	JIS T 0601-1:2017
IEC 60601-1:2005+A2:2020 <sup>*1</sup>		
IEC 60601-1-6:2010	EN 60601-1-6:2010	
IEC 60601-1-6:2010+A1:2013	EN 60601-1-6:2010+A1:2015	
IEC 60601-1-6:2010+A2:2020 <sup>*1</sup>		
IEC 60601-1-8:2006	EN 60601-1-8:2007	JIS T 60601-1-8:2012
IEC 60601-1-8:2006+A1:2012	EN 60601-1-8:2007+A1:2013+AC:2014	
IEC 60601-1-8:2006+A2:2020 <sup>*1</sup>		
IEC 60601-1-11:2010		
IEC 60601-1-11:2015		
IEC 60601-1-11:2015+A1:2020 <sup>*1</sup>		
IEC 60601-2-2:2009		JIS T 0601-2-2:2014
IEC 60601-2-2:2017		JIS T 0601-2-2:2020 <sup>*1</sup>
IEC 60601-2-10:2012	EN 60601-2-10:2015	JIS T 0601-2-10:2015
IEC 60601-2-10:2012+A1:2016	EN 60601-2-10:2015+A1:2016	
IEC 60601-2-16:2012	EN 60601-2-16:2015	JIS T 0601-2-16:2014
IEC 60601-2-16:2018		
IEC 60601-2-18:2009		JIS T 0601-2-18:2013
IEC 60601-2-24:2012		JIS T 0601-2-24:2018
IEC 60601-2-25:2011 <sup>*1</sup>		
IEC 60601-2-27:2011 <sup>*1</sup>		
IEC 60601-2-46:2016		
		JIS T 0601-2-204:2015
		JIS T 0601-2-205:2015
		JIS T 0601-2-206:2015
IEC 80601-2-30:2009	EN 80601-2-30:2010	
IEC 80601-2-30:2009+A1:2013	EN 80601-2-30:2010+A1:2015	JIS T 1115:2018
IEC 60601-2-37:2007 <sup>*1</sup>		JIS T 0601-2-37:2013 <sup>*1</sup>
IEC 60601-2-37:2007+A1:2015 <sup>*1</sup>		JIS T 0601-2-37:2018 <sup>*1</sup>
IEC 80601-2-60:2012 <sup>*1</sup>		JIS T 80601-2-60:2014 <sup>*1</sup>
IEC 80601-2-60:2019 <sup>*1</sup>		
IEC 80601-2-77:2019		

<sup>\*1</sup>: Added as of May 25, 2021

IEC 62304:2006  
IEC 62304:2006+A1:2015

EN 62304:2006

JIS T 2304:2012  
JIS T 2304:2017  
JIS T 5602:2014\*<sup>1</sup>  
JIS T 5701:2014\*<sup>1</sup>

ISO 6875:2011\*<sup>1</sup>  
ISO 7494-1:2011\*<sup>1</sup>

IEC 62366:2007  
IEC 62366:2007+A1:2014  
IEC 62366-1:2015  
IEC 62366-1:2015+A1:2020\*<sup>1</sup>

EN 62366:2008  
EN 62366:2008+A1:2015  
EN 62366-1:2015+AC:2015 JIS T 62366-1:2019

ISO 80601-2-56:2009\*<sup>1</sup>  
ISO 80601-2-56:2017\*<sup>1</sup>  
ISO 80601-2-56:2017+A1:2018\*<sup>1</sup>

JIS T 1140:2014\*<sup>1</sup>  
JIS T 7209:2007\*<sup>1</sup>  
JIS T 7209:2018\*<sup>1</sup>

ISO 8539:1996\*<sup>1</sup>  
ISO 80601-2-69:2014\*<sup>1</sup>

\*<sup>1</sup>: Added as of May 25, 2021

## **Voluntary EMC Laboratory Accreditation Center Inc.**