



JAB



Testing Laboratory
Accreditation
Certificate

Accreditation No. RTL04050

JFE Techno-Research Corporation
Functional Materials Solution Division
Medical Device Testing Center

**1-1, Minamiwatarida-cho, Kawasaki-ku, Kawasaki-shi,
Kanagawa, Japan**

meets the following criteria. On the basis of this, Japan Accreditation Board (JAB) grants accreditation to the said testing laboratory.

Applicable accreditation criteria	: JIS Q 17025:2005 (ISO/IEC 17025:2005)
Scope of accreditation	: Mechanical testing (As described in the appendix)
Premises covered by accreditation	: As described in the appendix.
Expiry date of accreditation	: January 31, 2019

This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system.

The management system requirements in ISO/IEC 17025:2005 meet the principles of ISO 9001:2008 and are aligned with its pertinent requirements.

Revised (3)
Initial accreditation

July 20, 2016
January 20, 2015

T. Oda, Chairman
Laboratory Accreditation Committee

Y. Iizuka, President
Japan Accreditation Board



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Accreditation Certificate Appendix

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Type of Laboratory	Testing Laboratory
Name of Laboratory	JFE Techno-Research Corporation Functional Materials Solution Division Medical Device Testing Center
Address	1-1, Minamiwatarida-cho, Kawasaki-ku, Kawasaki-shi, Kanagawa, Japan

1) Premises on which testing activities are performed

Name of Premise	JFE Techno-Research Corporation Functional Materials Solution Division Medical Device Testing Center	
Address of Premise	Postal Code	210-0855
	Address	1-1, Minamiwatarida-cho, Kawasaki-ku, Kawasaki-shi, Kanagawa, Japan
Testing service at permanent facilities or on site testing service	<input checked="" type="checkbox"/> Testing service at permanent facilities <input type="checkbox"/> On site testing service	

Scope of Accreditation

CODE OF CIT*1	M25.A11
NAME OF CIT	Medical Devices

*1 CIT: Classification of Item to be Tested

*2 TCT: Technical Classification of Test

CODE & NAME OF TCT*2	TEST METHOD STANDARD OR STANDARD OPERATING PROCEDURE (SECTION NO. LIMITED OR EXCLUDED)	TEST CONDITION etc.
B13.1 Tensile test	ASTM F1717 (8.1.2)	Test force up to 10 kN Tension-bending test included.
B13.2 Compression test	ASTM F1717 (8.1.1) ASTM F2077 (8) ASTM F2267	Test force up to 50 kN Compression-bending and compression-shear tests included.
B13. 3. 1 Bend test	JIS T 0312 4 JIS T 0313 4 ASTM F382 A1 ASTM F384 A1 ASTM F1264 A1 ASTM F2193 A2.5, A3.5, A4.7	Test force up to 10 kN
B13.15 Fatigue test	ASTM F1717 (8.2) ASTM F1798 (9) ASTM F2077 (9)* ISO 7206-4 ISO 7206-6 JIS T 0312 5 JIS T 0313 5 JIS T 6005* ISO 14801*	Test force up to 10 kN Test torque up to 100 N·m *: tests in air and at room temperature are only in scope. Test force up to 10 kN *: tests in air and at room temperature (20 +/- 5°C) are only in scope.



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CODE & NAME OF TCT*2	TEST METHOD STANDARD OR STANDARD OPERATING PROCEDURE (SECTION NO. LIMITED OR EXCLUDED)	TEST CONDITION etc.
	ASTM F382 A2 ASTM F384 A2 ASTM F1264 A3, A4 ASTM F2193 A2.5, A3.5, A4.7	
B13.18.2 Torsion test	JIS T 0311 6.2, 6.3** ASTM F543 A1, A2 ASTM F1264 A2 ASTM F2193 A1.5.2, A1.5.3 ASTM F1717 (8.1.3) ASTM F2077 (8)	Test torque up to 100 N·m **: the standard requires no axial force should be applied in torsional fracture test as in 6.2, but tests with necessary axial force to maintain the screwdriver bit in the screw head are in scope when it is directed or accepted by the clients. Test torque up to 100 N·m
B13.19 Other strength test	JIS T 0311 6.3 ASTM F543 A3 ASTM F2193 A1.5.4 ASTM F1798 (8)	Pull-out test of screws Test force up to 10 kN Test force up to 50 kN (axial compression), 10 kN (axial tension) Test torque up to 100 N·m (torsion)

Japan Accreditation Board