

COPY



Testing Laboratory

Accreditation Certificate

Accreditation No. RTL04050



***JFE Techno-Research Corporation
Structural Materials Solution Division Structural Materials
Evaluation Center Medical Device Testing Group***

***1-1, Minamiwatarida-cho, Kawasaki-ku, Kawasaki-shi,
Kanagawa, 210-0855 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 17025:2018 (ISO/IEC 17025:2017)
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, 2027

Revised	September 14, 2022
Renewed	February 1, 2023
Initial accreditation	January 20, 2015

A handwritten signature in blue ink, reading 'Y. Iizuka', is positioned above a horizontal line.

Y. Iizuka, President

Japan Accreditation Board

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Appendix

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Type of Laboratory	Testing Laboratory
Name of Laboratory	JFE Techno-Research Corporation Structural Materials Solution Division Structural Materials Evaluation Center Medical Device Testing Group
Address	1-1, Minamiwatarida-cho, Kawasaki-ku, Kawasaki-shi, Kanagawa, 210-0855 Japan

1) Premises on which testing activities are performed

Name of Premises	JFE Techno-Research Corporation Structural Materials Solution Division Structural Materials Evaluation Center Medical Device Testing Group		
Address of Premises	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

FIELD	M25 Mechanical Testing
CODE OF CIT*1	M25.A11
NAME OF CIT	Medical safety tool

*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 strength & elongation test	ASTM F1717(8.1.2)	Test force up to 10 kN Tension-bending test included.
B13.2 Compressive strength 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

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Type of Laboratory	Testing Laboratory
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CODE & NAME OF TCT*2	TEST METHOD STANDARD OR STANDARD OPERATING PROCEDURE (SECTION NO. LIMITED OR EXCLUDED)	TEST CONDITION etc.
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* ASTM F382 (A2) ASTM F384 (A2) ASTM F1264 (A3, A4) ASTM F2193 (A2.5, A3.5, A4.7)	Test force up to 10 kN Test torque up to 100 N·m *: test in air and at room temperature are only in scope. Test force up to 10 kN *: tests in air and at room temperature (20 °C +/- 5 °C) are only in scope
B13.18.2 Torsion torque 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 for 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

Issue No. : RTL04050-20220914