PERRY JOHNSON LABORATORY ACCREDITATION, INC.

Certificate of Accreditation

Perry Johnson Laboratory Accreditation, Inc. has assessed the Laboratory of:

MED Institute, Inc.

1330 Win Hentschel Blvd. STE 100, West Lafayette, IN 47906

(Hereinafter called the Organization) and hereby declares that Organization is accredited in accordance with the recognized International Standard:

ISO/IEC 17025:2005

This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system
(as outlined by the joint ISO-ILAC-IAF Communiqué dated January 2009):

Mechanical and Electrical Testing

(As detailed in the supplement)

Accreditation claims for such testing and/or calibration services shall only be made from addresses referenced within this certificate. This Accreditation is granted subject to the system rules governing the Accreditation referred to above, and the Organization hereby covenants with the Accreditation body's duty to observe and comply with the said rules.

For PJLA:

Tracy Szerszen
President/Operations Manager

Perry Johnson Laboratory Accreditation, Inc. (PJLA)
755 W. Big Beaver, Suite 1325
Troy, Michigan 48084

Initial Accreditation Date:	*Issue Date:*	*Expiration Date:*
November 2, 2015	November 2, 2015	February 28, 2018

Accreditation No.:	*Certificate No.:*
88632	L15-364

The validity of this certificate is maintained through ongoing assessments based on a continuous accreditation cycle. The validity of this certificate should be confirmed through the PJLA website: www.pjlabs.com

Certificate of Accreditation: Supplement

MED Institute, Inc.
1330 Win Hentschel Blvd. STE 100, West Lafayette, IN 47906
Contact: Justin Metcalf Phone: 765-463-1633

Accreditation is granted to the facility to perform the following testing:

FIELD OF TEST	ITEMS, MATERIALS OR PRODUCTS TESTED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED	RANGE (WHERE APPROPRIATE) AND DETECTION LIMIT
Electrical [F]	Medical Devices	Electrochemical Corrosion	ASTM F2129 ASTN F3044 ASTM G59 ASTM G71 Lab Developed Method ECOR-001	N/A
		Electrosurgical Accessory Electrical Testing	ANSI/AAMI/IEC 60601-2-2 Section 201.8.8.3.101 ANSI/AAMI/IEC 60601-2-2 Section 201.8.8.3.102 ANSI/AAMI/IEC 60601-2-2 Section 201.8.8.3.103 ANSI/AAMI/IEC 60601-2-2 Section 201.8.8.3.104 IEC 60601-2-18 Section 201.11.101.2 Lab Developed Method ECT-491	
Mechanical [F]		*MRI Testing (Displacement Force, Torque, RF Heating and Image Artifact)	ASTM F2052, F2119, F2182, F2213; Lab Developed Method MRI-400	
		Immersion Corrosion	ASTM F1980 ASTM G 31 ASTM 1089 Lab Developed Method ACOR-716	
		**Pulsatile Fatigue	ASTM F2477 ASTM F3036 ASTM E739 Lab Developed Method FATG -320	
		Tensile (up to 10000N) Stress/Strain Maximum Force	BS EN 1617 BS EN 1618 Annex B ASTM E8/E8M JIS T 3213 ASTM D412 BS EN 1615 Annex F JIS T 3247 ISO 7864 Lab Developed Methods PULT-204, -210,	10 KN
		Torque	ASTM A938; Lab Developed Method TORQ-553	±2.8 N·m

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Mechanical [F]	Medical Devices	Particulate Matter Generation	ASTM F2734 ASTM F2942 Lab Developed Methods PART -02[††], -03, -04, -05	2 µm to 400 µm
		**Simulated Use	ASTM F2081 ASTM F2079 ANSI/AAMI VP20 - 8.1 Lab Developed Method SIM-01	N/A
		**†Physical Bench Examination and Mechanical Bench Measurements	ISO 5084 ASTM D1777 Lab Developed Methods MED-007, MEAS-825, -829, -830, -832	
		Fatigue (Flat Plate, Bending, Axial, Torsional and Sling Radial)	ASTM F2942, ASTM E739 Lab Developed Methods FATG-401, -500, -700, -800, -900	± 12.7 mm ± 180° ± 2 225 N
		Flow	ASTM F1828 ANSI/AAMI VP20 Lab Developed Methods FLOW-100, -302	N/A
		Pressure	ANSI/AAMI VP20 Section 8.3.3.3 ISO 13938-1 Lab Developed Method PRES-01	-103 kPa to +207 KPa
		Securement	ASTM F2394 Lab Developed Method MEAS-100	N/A
		Radial Force	ASTM 3067 (segmented head apparatus method) Lab Developed Method RF-300	0.5 mm to 55 mm 0 N to 225 N
		**Radiopacity	ASTM F640 Lab Developed Method RAD-01	N/A
		Compression	ASTM E9 ASTM D695 ASTM F2606 Lab Developed Method COMP-220	10 KN

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Mechanical [F]	Medical Devices	Abrasion (Martindale)[††]	ASTM D4966 ISO 12947-1 ISO 12947-3 Lab Developed Method MART -100	N/A
		Yarn Testing	ASTM D2259 ASTM D1907 ASTM D2256 ASTM D2259 ASTM D1779 ASTM D1423 Lab Developed Method Yarn-100	
	Tubular vascular prostheses	See pg. 4 for details	ISO 7198	
	Intravascular catheters- Sterile and single-use catheters	See pg. 5 for details	ISO 10555-1	
	Angiographic catheters	See pg. 5 for details	ISO 10555-2	
	Balloon dilatation catheters	See pg. 5 for details	ISO 10555-4	
	Endovascular prostheses	See pg. 6 for details	ISO 25539-1	
	Vascular stents	See pg. 7 for details	ISO 25539-2	
	Vena cava filters	See pg. 8 for details	ISO 25539-3	
	Sterile single-use intravascular introducers, dilators and guidewires	See pg. 9 for details	ISO 11070	
	Cardiovascular implants - Tubular vascular prostheses	Visual Inspection	ISO 7198 section 8.1	
		Liquid Leakage Porosity Water Permeability Integral Water Permeability/Leakage Water Entry Pressure	ISO 7198 section 8.2	
		Strength Testing Circumferential Tensile Strength Longitudinal Tensile Strength Burst Strength Strength after Repeated Puncture	ISO 7198 section 8.3	

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Mechanical [F]	Cardiovascular implant Tubular vascular prostheses	Usable Length	ISO 7198 section 8.4	N/A
		Relaxed Internal Diameter	ISO 7198 section 8.5	
		Pressurized Internal Diameter	ISO 7198 section 8.6	
		Wall Thickness	ISO 7198 section 8.7.4.2	
		Suture Retention Strength	ISO 7198 section 8.8	
		Kink Diameter/Radius	ISO 7198 section 8.9	
		Dynamic Compliance	ISO 7198 section 8.10	
		Visual Inspection	ISO 7198 section 8.1	
	Intravascular catheters- Sterile and single-use catheters Part 1: General requirements Part 2: Angiographic catheters Part 4: Balloon dilatation catheters	Test method for corrosion resistance	ISO10555-1 Annex A	
		Method for determining peak tensile force	ISO10555-1 Annex B	
		Test Method for liquid leakage under pressure	ISO 10555-1 Annex C	
		Test method for air leakage into hub assembly during aspiration	ISO 10555-1 Annex D	
		Determination of flow rate	ISO 10555-1 Annex E	
		Test for burst pressure under static conditions	ISO 10555-1 Annex F	
		Power injection test for flow rate and device pressure	ISO 10555-1 Annex F	
		Test for freedom from leakage and damage under high static pressure conditions	ISO 10555-2 Annex A	
		Test for balloon rated burst pressure	ISO 10555-4 Annex A	
		Balloon Fatigue test for freedom from leakage and damage on inflation	ISO 10555-4 Annex B	
		Test for balloon deflation time	ISO 10555-4 Annex C	
		Test for balloon diameter to inflation pressure	ISO 10555-4 Annex D	

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Mechanical [F]	Cardiovascular implants- Endovascular devices Part 1:Endovascular prostheses	**Dimension verification and component dimensional compatibility	ISO 25539-1/Amd.1	N/A
		Profile/diameter test	ISO 25539-1/Amd.1	
		Assessment of hemostasis	ISO 25539-1/Amd.1	
		**Simulated use models	ISO 25539-1/Amd.1	
		**Visibility	ISO 25539-1/Amd.1	
		Force to deploy	ISO 25539-1/Amd.1	
		Balloon inflation and deflation time	ISO 25539-1/Amd.1	
		Balloon rated burst pressure	ISO 25539-1/Amd.1	
		Balloon volume to burst	ISO 25539-1/Amd.1	
		Balloon rated fatigue	ISO 25539-1/Amd.1	
		Bond Strength	ISO 25539-1/Amd.1	
		Torsional bond strength	ISO 25539-1/Amd.1	
		Tubing longitudinal tensile strength	ISO 25539-1/Amd.1	
		Dimensional verification	ISO 25539-1/Amd.1	
		Implant diameter to balloon inflation pressure	ISO 25539-1/Amd.1	
		Implant length to diameter relationship	ISO 25539-1/Amd.1	
		Recoil	ISO 25539-1/Amd.1	
		Integral water permeability/leakage	ISO 25539-1/Amd.1	
		Water entry pressure	ISO 25539-1/Amd.1	
		Water permeability	ISO 25539-1/Amd.1	
		Burst/circumferential strength	ISO 25539-1/Amd.1	
		Crush Resistance	ISO 25539-1/Amd.1	
		Flex/Kink	ISO 25539-1/Amd.1	
		Local compression	ISO 25539-1/Amd.1	
		Longitudinal tensile strength	ISO 25539-1/Amd.1	

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Mechanical [F]	Cardiovascular implants- Endovascular devices Part 1:Endovascular prostheses	Migration resistance	ISO 25539-1/Amd.1	N/A
		Pull test for modular components	ISO 25539-1/Amd.1	
		Radial force	ISO 25539-1/Amd.1	
		Strength after repeated puncture	ISO 25539-1/Amd.1	
		Strength of graft to stent/attachment system bond	ISO 25539-1/Amd.1	
		Corrosion assessment	ISO 25539-1/Amd.1 Annex D5.3.18	
		Fatigue and durability test (pulsatile)	ISO 25539-1/Amd.1	
	Cardiovascular implants- Endovascular devices Part 2:Endovascular prostheses	**Dimension verification and component dimensional compatibility	ISO 25539-2 Annex	
		Profile/diameter test	ISO 25539-2 Annex	
		Assessment of hemostasis	ISO 25539-2 Annex	
		**Simulative use	ISO 25539-2 Annex	
		**Visibility	ISO 25539-2 Annex	
		Force to deploy	ISO 25539-2 Annex	
		Balloon inflation and deflation time	ISO 25539-2 Annex	
		Balloon rated burst pressure	ISO 25539-2 Annex	
		Balloon rated fatigue	ISO 25539-2 Annex	
		Bond Strength	ISO 25539-2 Annex	
		Torsional bond strength	ISO 25539-2 Annex	
		Stent diameter to balloon inflation pressure	ISO 25539-2 Annex	
		Dimensional verification and stent length to diameter relationship	ISO 25539-2 Annex	
		Recoil	ISO 25539-2 Annex	

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Mechanical [F]	Cardiovascular implants-Endovascular devices – Part 2:Endovascular prostheses	Crush resistance with radially applied load	ISO 25539-2 Annex	N/A
		Crush resistance with parallel plates	ISO 25539-2 Annex	
		Flex/kink	ISO 25539-2 Annex	
		Local compression	ISO 25539-2 Annex	
		Radial Force	ISO 25539-2 Annex	
		Corrosion assessment	ISO 25539-2 Annex	
		Fatigue durability test	ISO 25539-2 Annex	
		Dislodgment force	ISO 25539-2 Annex	
		Dogboning	ISO 25539-2 Annex	
		Profile effect/flaring	ISO 25539-2 Annex	
		Stent free surface area and stent outer surface area	ISO 25539-2 Annex	
		Acute coating integrity	ISO 25539-2 Annex	
	Cardiovascular implants-Endovascular devices – Part 3:Vena cava filters	**Dimension verification and component dimensional compatibility	ISO 25539-3 Annex D5.1.1 and D5.5.1	
		**Simulative use	ISO 25539-3 Annex D.5.1.2	
		Force to deploy	ISO 25539-3 Annex D.5.1.3	
		**Visibility	ISO 25539-3 Annex D.5.1.4 and D5.5.4	
		Clot trapping	ISO 25539-3 Annex D.5.2.1	
		Fatigue/durability	ISO 25539-3 Annex D.5.2.2	
		Filter dimensional verification	ISO 25539-3 Annex D.5.2.3	
		Filter tensile strength	ISO 25539-3 Annex D.5.2.4	
		Migration resistance	ISO 25539-3 Annex D.5.2.5	
		Radial force	ISO 25539-3 Annex D.5.2.6	
		Visual inspection	ISO 25539-3 Annex D.5.2.8	

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Mechanical [F]	Cardiovascular implants-Endovascular devices - Part 3:Vena cava filters	Tensile strength	ISO 25539-3 Annex D.5.3.1, D.5.4.3, D.5.6.1 and D.5.7.3	N/A
		Torsional bond strength	ISO 25539-3 Annex D.5.3.2, D.5.4.4, D.5.6.2 and D.5.7.4	
		Catheter burst	ISO 25539-3 Annex D.5.4.1 and D.5.7.1	
		Power injection	ISO 25539-3 Annex D.5.4.2 and D.5.7.2	
		Simulated use (endovascular retrieval/conversion system)	ISO 25539-3 Annex D.5.5.2	
		Force to retrieve/convert	ISO 25539-3 Annex D.5.5.3	
	Sterile single-use intravascular introducers, dilators and guidewires	Test method for corrosion resistance	ISO 11070 Annex B	
		Determination of force at break of introducer catheters, sheath introducers and dilators	ISO 11070 Annex C	
		Test for liquid leakage from sheath introducers under pressure	ISO 11070 Annex D	
		Test for liquid leakage through haemostasis valves of sheath introducers	ISO 11070 Annex E	
		Test for fracture of guide wires	ISO 11070 Annex F	
		Test for resistance of guide wires damage by flexing	ISO 11070 Annex H	
		Determination of strength of union of needle hub and needle	ISO 11070 Annex I	

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1. The presence of a superscript F means that the laboratory performs testing of the indicated parameter at its fixed location. Example: Outside Micrometer ^{F} would mean that the laboratory performs this testing at its fixed location.

2. *MRI testing is conducted using clinical scanners at offsite facilities.

3. **Radiographic activity, when performed as part of these tests, is performed using equipment at:
   Purdue University
   Lynn Hall
   625 Harrison St.
   West Lafayette, IN 47906

4. † SEM and High resolution X-ray, when performed, is performed using equipment at:
   CRI
   1 Geddes way
   West Lafayette, IN 47906

5. †† Testing is performed using equipment at:
   CRI
   1 Geddes way
   West Lafayette, IN 47906