PERRY JOHNSON LABORATORY ACCREDITATION, INC.

Certificate of Accreditation

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

Biomedical Device Consultants & Laboratories, LLC (BDC Laboratories)

4060 Youngfield St., Wheat Ridge, CO 80033

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

ISO/IEC 17025:2017

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 April 2017):

Electrical, Dimensional Inspection and Mechanical 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

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

Initial Accreditation Date:	*Issue Date:*	*Expiration Date:*
September 29, 2015	September 17, 2023	December 31, 2025

Accreditation No:	*Certificate No:*
87132	L23-693

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

Biomedical Device Consultants & Laboratories, LLC
(BDC Laboratories)
4060 Youngfield St., Wheat Ridge, CO 80033
Contact Name: Devin McBlair Phone: 303-456-4665

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]	Implantable Medical Devices	Electrochemical Corrosion, Cyclic Potentiodynamic Polarization	ASTM F2129 Lab Developed Method TM-0080	± 600 mA, ± 800 mV
		Electrochemical Corrosion, Galvanic	ASTM F3044 Lab Developed Method TM-0083	± 600 mA, ± 800 mV
Mechanical [F]	Endovascular Devices, Vascular Prostheses	Pulsatile Durability	ASTM F2477 ISO 25539-1, Annex D.5.2.3.2 ISO 25539-2, Annex D.5.3.3.2 Lab Developed Method TM-0002	0.5 mm to 65 mm
		Determination of Dynamic Compliance and Pressurized Internal Diameter	ISO 7198, Annex A.5.9 ISO 7198, Annex A.5.5 Lab Developed Method TM-0001	0.5 mm to 49.5 mm
	Cardiac Valve Prostheses	Hydrodynamic Valve Performance Steady Flow	ISO 5840-1, Annex I Lab Developed Method TM-0077	Forward Flow Rate: 0 L/min to 35 L/min Back Pressure: 10 mmHg up to 300 mmHg
		Hydrodynamic Valve Performance Pulsatile Flow	ISO 5840-2, Annex F ISO 5840-3, Annex C Lab Developed Method TM-0013	Flow Rate: 0 L/min to 10 L/min Driving Waveform: Sinusoidal, Arbitrary Frequency: 2 bpm to 240 bpm
		Durability	ISO 5840-1, Annex J Lab Developed Method TM-0014	Excitation Waveforms: Sine & Modified Sine, Arbitrary Operating Frequency: 5 Hz to 50 Hz
	Medical Devices	Acute Particulate Matter Generation and Coating Integrity	ASTM F2743 ASTM F3320 Lab Developed Methods TM-0022 and TM-0081	2 µm to 1,000 µm
		Examination Testing: Surface Guidewire Fracture Guidewire Flex Coating Integrity	ISO 25539-3 Annex D.5.2.8 ISO 10555-1 Clause 4.4 ISO 10555-3 Clause 4.3 ISO 10555-6 Clause 4.5.2 ISO 11070 Clause 4.3 ISO 11070 Annex F ISO 11070 Annex G ASTM F2743 ASTM F3320 Lab Developed Method TM-0035	Up to 200 X

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Mechanical [F]	Medical Devices	Visual Inspections	ISO 25539-3 Annex D.5.2.8 ISO 10555-1 Clause 4.4 ISO 10555-3 Clause 4.3 ISO 10555-6 Clause 4.5.2 ISO 11070 Clause 4.3 Lab Developed Method TM-0035	Up to 200 X
		Tensile Strength	ASTM F2394 ISO 25539-1 Annex D.5.2.8.3 ISO 25539-2 Annex D.5.2.9 ISO 25539-3 Annex D.5.2.4 ISO 25539-3 Annex D.5.3.1 ISO 25539-3 Annex D.5.4.3 ISO 25539-3 Annex D.5.6.1 ISO 25539-3 Annex D.5.7.3 ISO 20697 Annex D, Annex E ISO 7198, Annex A.5.2.3 ISO 7198, Annex A.5.2.4 ISO 7198, Annex A.5.2.7 ISO 7198, Annex A.5.7 ISO 10555-1 Annex B ISO 11070 Annex C ISO 11070 Annex H ISO 34-1 Section 10 Lab Developed Method TM-0015	≤ 1 kN
	Endovascular Prostheses, Vascular Stents	Kink Radius	ISO 25539-1 Annex D.5.2.5.5 ISO 25539-2 Annex D.5.3.4.5 ISO 7198 Annex A.5.8 ASTM F3505 Lab Developed Method TM-0030	Up to 200 mm
		Torsional Durability	ISO 25539-1 Annex D.5.2.3.6 ISO 25539-2 Annex D.5.3.3.5 ASTM F2942 Lab Developed Method TM-0082	Angle of twist -10 to 90°
	Guidewires	Guidewire Flex	ISO 11070 Annex G Lab Developed Method TM-0035	Up to 200 X
	Coated Medical Devices	Coating Integrity Inspection	ASTM F2743 ASTM F3320 Lab Developed Method TM-0035	Coated Medical Devices
	Implantable Medical Devices [FO]	Measurement of Radio Frequency Induced Heating	ASTM F2182 Lab Developed Method TM-0053	Field Strengths: 1.5 T, 3 T
		Evaluation of MRI Artifacts from Passive Implants	ASTM F2119 Lab Developed Method TM-0055	

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Mechanical [F]	Implantable Medical Devices [FO]	Measurement of Magnetically Induced Torque	ASTM F2213 Lab Developed Method TM-0052	Field Strengths: 1.5 T, 3 T
		Measurement of Magnetically Induced Displacement Force	ASTM F2052 Lab Developed Method TM-0054	
	Endovascular prostheses, Vascular stents, Vena cava filters	Radial Force	ASTM F3067 ISO 25539-1 Annex D.5.2.5.4 ISO 25539-2 Annex D.5.3.4.4 ISO 25539-3 Annex D.5.2.6 Lab Developed Method TM-0007	Up to 16 mm ≤ 660N Up to 60 mm ≤ 930 N
	Intravascular Catheters	Catheter Recirculation	Lab Developed Method TM-0006	Up to 100 %
Dimensional Inspection [F]	Endovascular prostheses, Vascular stents	Length to Diameter Relationship	ISO 25539-1 Annex D.5.2.7.3 ISO 25539-2 Annex D.5.3.5.3 Lab Developed Method TM-0041	Up to 2 000 mm
		Elastic Recoil	ISO 25539-1 Annex D.5.2.7.4 ISO 25539-2 Annex D.5.3.5.4 ASTM F2079 Lab Developed Method TM-0041	Up to 152 mm
	Endovascular prostheses, Vascular stents, Balloon dilatation catheters	Diameter to Balloon Inflation Pressure	ISO 25539-1 Annex D.5.2.7.2 ISO 25539-2 Annex D.5.3.5.2 ISO 25539-2 Annex D.5.5.2 ISO 10555-4 Annex D ASTM F2081 Lab Developed Method TM-0041	
	Medical Devices	Dimensional Verification	ISO 25539-1 Annex D.5.1.2 ISO 25539-1 Annex D.5.2.7.1 ISO 25539-2 Annex D.5.2.3 ISO 25539-2 Annex D.5.3.5.1 ISO 25539-3 Annex D.5.1.1 ISO 25539-3 Annex D.5.5.1 ISO 25539-3 Annex D.5.2.3 ISO 10555-1 Clause 5 Lab Developed Method TM-0041 ASTM F2081	Up to 2 000 mm
	Vascular stents	Profile Effect/Flaring	ISO 25539-2 Annex D.5.2.7 Lab Developed Method TM-0041 ASTM F2081	Up to 152 mm
		Dogboning	ISO 25539-2 Annex D.5.2.2.5 Lab Developed Method TM-0041	Up to 152 mm
	Vascular prostheses	Microscopic Porosity (inter-nodal distance)	ISO 7198, Annex A.5.1.1.3 Lab Developed Method TM-0041	Up to 152 mm
		Usable Length/Width	ISO 7198 Annex A.5.3 Lab Developed Method TM-0041	

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Dimensional Inspection [F]	Vascular prostheses	Relaxed Inner Diameter	ISO 7198 Annex A.5.4 Lab Developed Method TM-0041	Up to 152 mm
		Wall Thickness	ISO 7198 Annex A.5.6 Lab Developed Method TM-0041	Up to 13 mm

1. The presence of a superscript F means that the laboratory performs testing of the indicated parameter at its fixed location. Example: Mechanical [F] would mean that the laboratory performs this testing at its fixed location.

2. The presence of a superscript FO means that the laboratory performs testing of the indicated parameter both at its fixed location and onsite at customer locations. Example: Outside Micrometer[FO] would mean that the laboratory performs this testing at its fixed location and onsite at customer locations.