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 Street, 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
Revision Date:	*Accreditation No.:*	*Certificate No.:*
October 21, 2024	87132	L23-693-R1

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 Street, Wheat Ridge, CO 80033
Contact Name: Devin McBlair Phone: 303-456-4665

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

FLEX CODE	FIELD OF TEST	ITEMS, MATERIALS, OR PRODUCTS TESTED	COMPONENT, CHARACTERISTIC, PARAMETER TESTED	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED
F1, F2, F4	Electrical [F]	Implantable Medical Devices	Electrochemical Corrosion, Cyclic Potentiodynamic Polarization	ASTM F2129 Lab Developed Method TM-0080	Electrochemical
F1, F2, F4			Electrochemical Corrosion, Galvanic	ASTM F3044 Lab Developed Method TM-0083	
F1, F2, F4	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	Cyclic Radial Excitation
F1, F2, F4			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	
F1, F2, F4		Cardiac Valve Prostheses Heart Valve Repair Devices	Hydrodynamic Valve Performance Steady Flow	ISO 5840-1, Annex I Lab Developed Method TM-0077	Constant Flow / Constant Differential Pressure
F1, F2, F4			Hydrodynamic Valve Performance Pulsatile Flow	ISO 5840-2, Annex F ISO 5840-3, Annex C Lab Developed Method TM-0013	Pulsatile Flow / Pulsatile Differential Pressure
F1, F2, F4			Durability	ISO 5840-1, Annex J ISO 5910 Annex M.2.3 Lab Developed Method TM-0014	Cyclic Differential Pressure
F1, F2, F4		Medical Devices	Acute Particulate Matter Generation and Coating Integrity	ASTM F2743 ASTM F3320 ISO 10555-1 Clause 4.17 Lab Developed Methods TM-0022 and TM-0081	Light Obscuration / Optical Microscopy
F1, F2, F4			Examination Testing: Surface Guidewire Fracture Guidewire Flex Coating Integrity	ISO 10555-1 Clause 4.7 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	Visual / Optical Microscopy

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F1, F2, F4	Mechanical [F]	Medical Devices	Visual Inspections	ISO 10555-1 Clause 4.7 ISO 10555-3 Clause 4.3 ISO 10555-6 Clause 4.5.2 ISO 11070 Clause 4.3 Lab Developed Method TM-0035	Visual / Optical Microscopy
F1, F2, F4			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.5.3.6 ISO 25539-3 Annex D.5.4.1 ISO 25539-3 Annex D.5.6.5 ISO 25539-3 Annex D.5.7.5 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	Axial Loading
F1, F2, F4		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	Reduction of Radius of Curvature
F1, F2, F4			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	Cyclic Twisting
F1, F2, F4		Guidewires	Guidewire Flex	ISO 11070 Annex G Lab Developed Method TM-0035	Visual / Optical Microscopy
F1, F2, F4		Coated Medical Devices	Coating Integrity Inspection	ASTM F2743 ASTM F3320 Lab Developed Method TM-0035	

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F1, F2, F4	Mechanical [F]	Implantable Medical Devices [FO]	Measurement of Radio Frequency Induced Heating	ASTM F2182 Lab Developed Method TM-0053	Magnetic Resonance Imaging (MRI)
F1, F2, F4			Evaluation of MRI Artifacts from Passive Implants	ASTM F2119 Lab Developed Method TM-0055	
F1, F2, F4			Measurement of Magnetically Induced Torque	ASTM F2213 Lab Developed Method TM-0052	Resistance to Magnetically Induced Rotation
F1, F2, F4			Measurement of Magnetically Induced Displacement Force	ASTM F2052 Lab Developed Method TM-0054	Resistance to Magnetically Induced Translation
F1, F2, F4		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.5.3.8 Lab Developed Method TM-0007	Expansion / Reduction of Diameter
F1, F4		Intravascular Catheters	Catheter Recirculation	Lab Developed Method TM-0006	Dialysis Catheter Flow Within Pulsatile Flow Field
F1, F2, F4		Endovascular Devices	Balloon Deflation Time	ANSI/AAMI/ISO 25539-1 Annex D.5.1.2 ISO 25539-2 ISO 10555-4 Lab Developed Method TM-0011	Time of Event
F1, F2, F4		Vascular prosthesis, endovascular prosthesis, vascular stents, and heart valve frames	Axial tension and compression	ANSI/AAMI/ISO 25539-1 Annex D.5.2.3.3, D.5.2.3.4, or D.5.2.3.5 ISO 25539-2 Annex D.5.3.3.3, D.5.3.3.4, or D.5.3.3.6 ANSI/AAMI/ISO 25539-3:2011 Annex D.5.3.4 ISO 5840-1 Annex K.6 ISO 5910 Annex M.2.4 ASTM F2942 Lab Developed Method TM-0057	Cyclic Axial Loading

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F1, F2, F4	Mechanical [F]	Vascular, endovascular, cardiac valve prosthesis, cardiac occluders, and delivery systems.	Simulated Use	ANSI/AAMI/ISO 25539-1 Annex D.5.1.5, and D.5.1.4. ISO 25539-2 Annex D.5.2.8 ANSI/AAMI/ISO 25539-3 Annex D.5.2.3, D.5.4.3, D.5.6.3, and D.5.7.3 ISO 5840-2 Sub-clause 7.2.8 ISO 5840-3:2021 Annex D ISO 22679:2021 Annex M	Visual / Optical Microscopy Measurement of Load
F1, F2, F4	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	Diameter Constrained
F1, F2, F4			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	Balloon Expansion and Deflation
F1, F2, F4		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	Balloon Expansion
F1, F2, F4		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.5.2.1 ISO 25539-3 Annex D.5.3.5 ISO 25539-3 Annex D.5.6.1 ISO 25539-3 Annex D.5.7.1 ISO 10555-1 Clause 5 Lab Developed Method TM-0041 ASTM F2081	Contact / Non-Contact Measurement
F1, F2, F4		Vascular stents	Profile Effect/Flaring	ISO 25539-2 Annex D.5.2.7 Lab Developed Method TM-0041 ASTM F2081	Bending with Simulated Use
F1, F2, F4			Dogboning	ISO 25539-2 Annex D.5.2.2.5 Lab Developed Method TM-0041	Balloon Expansion
F1, F2, F4		Vascular prostheses	Microscopic Porosity (inter-nodal distance)	ISO 7198, Annex A.5.1.1.3 Lab Developed Method TM-0041	Scanning Electron Microscope (SEM)
F1, F2, F4			Usable Length/Width	ISO 7198 Annex A.5.3 Lab Developed Method TM-0041	Contact / Non-Contact Measurement
F1, F2, F4			Relaxed Inner Diameter	ISO 7198 Annex A.5.4 Lab Developed Method TM-0041	
F1, F2, F4			Wall Thickness	ISO 7198 Annex A.5.6 Lab Developed Method TM-0041	

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

1. The presence of a superscript F means that the laboratory performs testing of the indicated parameter at its fixed location.

2. Flex Code:
   F0-Fixed scope item. No deviations allowed to the line item as identified, except for updating to the most recent version of an accredited standard method after verification
   F1-Laboratory has the capability to test a new item, material, matrix, or product similar in composition to item, material, matrix, or product identified on the scope
   F2-Laboratory has the capability to introduce the newest revision of an accredited authoritative standard method (with no modifications) identified on the scope
   F3-Laboratory has the capability to introduce a parameter/component/analyte to an accredited test method identified on the scope
   F4-Laboratory has the capability to introduce a new revision of an accredited non-standard method using the same technology or technique identified on the scope
   F5-Laboratory has the capability to introduce a validated method that is equivalent to an accredited method (using same technology or technique) identified on the scope