PERRY JOHNSON LABORATORY ACCREDITATION, INC.

Certificate of Accreditation

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

Biomedical Device Consultants & Laboratories, LLC (BDC Laboratories)

4060 Youngfield Street, Wheat Ridge, CO 80033

and hereby declares that the Organization is accredited in accordance with the recognized International Standard:

ISO/IEC 17025:2017

Whereby, technical competence has been confirmed for the associated scope supplement, in the fields of:

Electrical, Dimensional Inspection, and Mechanical Testing

(As detailed in the supplement)

Accreditation claims for conformity assessment activities shall only be made from the addresses referenced within this certificate and shall apply solely to those activities identified in the related scope. This Accreditation is granted subject to the Accreditation Body rules governing the Accreditation referred to above, and the Organization hereby commits to observing and complying with those rules in their entirety.

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	October 05, 2025	December 31, 2027

Accreditation No.:	*Certificate No.:*
87132	L25-750

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: Lucas Calloway Phone: 303-456-4665

Accreditation is granted to the facility to perform the following conformity assessment activities:

FIELD OF TEST	ITEMS, MATERIALS, OR PRODUCTS TESTED	COMPONENT, CHARACTERISTIC, PARAMETER TESTED	SPECIFICATION OR STANDARD METHOD	TECHNOLOGY OR TECHNIQUE USED	FLEX CODE	LOCATION OF ACTIVITY
Electrical	Implantable Medical Devices	Electrochemical Corrosion, Cyclic Potentiodyanic Polarization	ASTM F2129 TM-0080	Potentiostat	F1, F2, F4	F
Electrical	Implantable Medical Devices	Electrochemical Corrosion, Galvanic	ASTM F3044 TM-0083	Potentiostat	F1, F2, F4	F
Mechanical	Endovascular Devices, Vascular Prostheses	Pulsatile Durability	ASTM F2477 AAMI/ANSI/ISO 25539-1 Annex D.5.2.3.2 ISO 25539-2 Annex D.5.3.3.2 TM-0002	Cyclic Radial Excitation	F1, F2, F4	F
Mechanical	Endovascular Devices, Vascular Prostheses	Determination of Dynamic Compliance and Pressurized Internal Diameter	ISO 7198 Annex A.5.9 ISO 7198 Annex A.5.5 TM-0001	Cyclic Radial Excitation	F1, F2, F4	F
Mechanical	Cardiac Valve Prostheses Heart Valve Repair Devices	Hydrodynamic Valve Performance Steady Flow	ISO 5840-1 Annex I TM-0077	Constant Flow, Constant Differential Pressure	F1, F2, F4	F
Mechanical	Cardiac Valve Prostheses Heart Valve Repair Devices	Hydrodynamic Valve Performance Pulsatile Flow	ISO 5840-2 Annex F ISO 5840-3 Annex C TM-0013	Pulsatile Flow, Pulsatile Differential Pressure	F1, F2, F4	F
Mechanical	Cardiac Valve Prostheses Heart Valve Repair Devices	Durability	ISO 5840-1 Annex J ISO 5910 Annex M.2.3 TM-0014	Cyclic Differential Pressure	F1, F2, F4	F
Mechanical	Medical Devices	Acute Particulate Matter Generation and Coating Integrity	ASTM F2743 ASTM F3320 ISO 10555-1 Clause 4.17 ISO 25539-2 Annex D.5.2.6 TM-0022 TM-0081	Light Obscuration, Optical Microscopy	F1, F2, F4	F

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Mechanical	Medical Devices	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 TM-0035	Visual, Optical Microscopy	F1, F2, F4	F
Mechanical	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 TM-0035	Visual, Optical Microscopy	F1, F2, F4	F
Mechanical	Medical Devices	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 TM-0015	Axial Loading	F1, F2, F4	F

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Mechanical	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 TM-0030	Reduction of Radius of Curvature	F1, F2, F4	F
Mechanical	Endovascular Prostheses, Vascular Stents	Torsional Durability	ISO 25539-1 Annex D.5.2.3.6 ISO 25539-2 Annex D.5.3.3.5 ASTM F2942 TM-0082	Cyclic Twisting	F1, F2, F4	F
Mechanical	Guidewires	Guidewire Flex	ISO 11070 Annex G TM-0035	Visual, Optical Microscopy	F1, F2, F4	F
Mechanical	Coated Medical Devices	Coating Integrity Inspection	ASTM F2743 ASTM F3320 TM-0035	Visual, Optical Microscopy	F1, F2, F4	F
Mechanical	Implantable Medical Devices	Measurement of Radio Frequency Induced Heating	ASTM F2182 TM-0053	Magnetic Resonance Imaging (MRI)	F1, F2, F4	F, O
Mechanical	Implantable Medical Devices	Evaluation of MRI Artifacts from Passive Implants	ASTM F2119 TM-0055	Magnetic Resonance Imaging (MRI)	F1, F2, F4	F, O
Mechanical	Implantable Medical Devices	Measurement of Magnetically Induced Torque	ASTM F2213 TM-0052	Resistance to Magnetically Induced Rotation	F1, F2, F4	F, O
Mechanical	Implantable Medical Devices	Measurement of Magnetically Induced Displacement Force	ASTM F2052 TM-0054	Resistance to Magnetically Induced Translation	F1, F2, F4	F, O
Mechanical	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 TM-0007	Expansion, Reduction of Diameter	F1, F2, F4	F

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Mechanical	Intravascular Catheters	Catheter Recirculation	TM-0006	Dialysis Catheter Flow Within Pulsatile Flow Field	F1, F4	F
Mechanical	Endovascular Devices	Balloon Deflation Time	ANSI/AAMI/ISO 25539-1 Annex D.5.1.2 ISO 25539-2 ISO 10555-4 TM-0011	Time of Event	F1, F2, F4	F
Mechanical	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 ANSI/AAMI/ISO 25539-1 Annex D.5.2.3.4 ANSI/AAMI/ISO 25539-1 Annex D.5.2.3.5 ISO 25539-2 Annex D.5.3.3.3 ISO 25539-2 Annex D.5.3.3.4 ISO 25539-2 Annex 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 TM-0057	Cyclic Axial Loading	F1, F2, F4	F

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Mechanical	Vascular, endovascular, cardiac valve prosthesis, cardiac occluders, and delivery systems.	Simulated Use	ANSI/AAMI/ISO 25539-1 Annex D.5.1.5 ANSI/AAMI/ISO 25539-1 D.5.1.4 ISO 25539-2 Annex D.5.2.8 ANSI/AAMI/ISO 25539-3 ANSI/AAMI/ISO 25539-3 Annex D.5.2.3 ANSI/AAMI/ISO 25539-3 Annex D.5.4.3 ANSI/AAMI/ISO 25539-3 Annex D.5.6.3 ANSI/AAMI/ISO 25539-3 Annex 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	F
Dimensional Inspection	Endovascular prostheses, Vascular stents	Length to Diameter Relationship	ANSI/AAMI/ISO 25539-1 Annex D.5.2.7.3 ISO 25539-2 Annex D.5.3.5.3 TM-0041	Diameter Constrained	F1, F2, F4	F
Dimensional Inspection	Endovascular prostheses, Vascular stents	Elastic Recoil	ANSI/AAMI/ISO 25539-1 Annex D.5.2.7.4 ISO 25539-2 Annex D.5.3.5.4 ASTM F2079 TM-0041	Balloon Expansion and Deflation	F1, F2, F4	F
Dimensional Inspection	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 TM-0041	Balloon Expansion	F1, F2, F4	F

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Dimensional Inspection	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 ASTM F2081 TM-0041	Contact, Non-Contact Measurement	F1, F2, F4	F
Dimensional Inspection	Vascular stents	Profile Effect/Flaring	ISO 25539-2 Annex D.5.2.7 ASTM F2081 TM-0041	Bending with Simulated Use	F1, F2, F4	F
Dimensional Inspection	Vascular stents	Dog boning	ISO 25539-2 Annex D.5.2.2.5 TM-0041	Balloon Expansion	F1, F2, F4	F
Dimensional Inspection	Vascular prostheses	Microscopic Porosity (inter-nodal distance)	ISO 7198, Annex A.5.1.1.3 TM-0041	Scanning Electron Microscope (SEM)	F1, F2, F4	F
Dimensional Inspection	Vascular prostheses	Usable Length/Width	ISO 7198 Annex A.5.3 TM-0041	Contact, Non-Contact Measurement	F1, F2, F4	F
Dimensional Inspection	Vascular prostheses	Relaxed Inner Diameter	ISO 7198 Annex A.5.4 TM-0041	Contact, Non-Contact Measurement	F1, F2, F4	F
Dimensional Inspection	Vascular prostheses	Wall Thickness	ISO 7198 Annex A.5.6 TM-0041	Contact, Non-Contact Measurement	F1, F2, F4	F

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Accreditation is granted to the facility to perform the following conformity assessment activities:

1. Location of activity:

Location	Location
F	Conformity assessment activity is performed at the CABs fixed facility

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