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):

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	December 4, 2021	December 31, 2023

Accreditation No:	*Certificate No:*
87132	L21-741

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: Michael Baird 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	± 600 mA, ± 800 mV
		Electrochemical Galvanic Corrosion	ASTM F3044	± 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	0.5 mm to 65 mm
		Determination of Dynamic Compliance	ISO 7198, Annex A.5.9	0.5 mm to 49.5 mm
	Cardiac Valve Prostheses	Hydrodynamic Valve Performance Steady Flow	ISO 5840-1, Annex I	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	Flow Rate: 0 L/min to 10 L/min Driving Waveform: Sinusoidal, Arbitrary Frequency: 2 bpm to 240 bpm
		Durability Testing	ISO 5840-1, Annex J	Excitation Waveforms: Sine & Modified Sine, Arbitrary Operating Frequency: 1 Hz to 50 Hz
	Medical Devices	Acute Particulate Matter Generation and Coating Integrity	ASTM F2743 ASTM F3320	2 µm to 1000 µm

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Mechanical[FO]	Implantable Medical Devices	Measurement of Radio Frequency Induced Heating	ASTM F2182	Field Strengths: 1.5 T, 3 T
		Evaluation of MRI Artifacts from Passive Implants	ASTM F2119	
		Measurement of Magnetically Induced Torque	ASTM F2213	
		Measurement of Magnetically Induced Displacement Force	ASTM F2052	

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 offsite locations. Example: Mechanical[FO] would mean that the laboratory performs this testing at its fixed location and using clinical scanners at offsite facilities.