

PERRY JOHNSON LABORATORY ACCREDITATION, INC.

Certificate of Accreditation

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

Medical Murray

400 North Rand Road, North Barrington, IL 60010

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:

Mechanical and Dimensional 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: June 17. 2021 Issue Date:

June 01, 2025

Expiration Date: July 31, 2027

Accreditation No.: 108231

Certificate No.: L25-417

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: <u>www.pjlabs.com</u>



Medical Murray

400 North Rand Road, North Barrington, IL 60010 Contact Name: Rachel Martin Phone: 847-847-3700

Accreditation is	granted to the	facility to	perform the	following	conformity	vassessment activities:
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FIELD	ITEMS, MATERIALS,	COMPONENT, CHARACTERISTIC,	SPECIFICATION OR	TECHNOLOGY OR TECHNIQUE USED	FLEX CODE	LOCATION
OF TEST	OR PRODUCTS TESTED	PARAMETER TESTED	STANDARD METHOD			OF ACTIVITY
Mechanical	Small-Bore Connectors for	Leakage by Pressure Decay	ISO 80369-7 Section	Leak tester	F1, F2	F
	Liquids and Gases in		6.1.2	Thermometer/hygrometer		
	Healthcare Applications –		ISO 80369-20 Annex B	ISO 80369-7 reference connector		
	Connectors for Intravascular			Force gauge		
	or Hypodermic Applications			Torque gauge		
Mechanical	Small-Bore Connectors for	Positive Pressure Liquid	ISO 80369-7 Section	Hydraulic pressure tester	F1, F2	F
	Liquids and Gases in	Leakage	6.1.3	Thermometer/hygrometer		
	Healthcare Applications –		ISO 80369-20 Annex C	ISO 80369-7 reference connector		
	Connectors for Intravascular			Force gauge		
	or Hypodermic Applications			Torque gauge		
Mechanical	Small-Bore Connectors for	Sub-atmospheric Pressure Air	ISO 80369-7 Section 6.2	Vacuum pump/gauge	F1, F2	F
	Liquids and Gases in	Leakage	ISO 80369-20 Annex D	Thermometer/hygrometer		
	Healthcare Applications –			ISO 80369-7 reference connector		
	Connectors for Intravascular			Force gauge		
	or Hypodermic Applications			Torque gauge		
				Timer		
Mechanical	Small-Bore Connectors for	Stress Cracking	ISO 80369-7 Section 6.3	Hydraulic pressure tester or Leak	F1, F2	F
	Liquids and Gases in		ISO 80369-20 Annex E	tester		
	Healthcare Applications –			Thermometer/hygrometer		
	Connectors for Intravascular			ISO 80369-7 reference connector		
	or Hypodermic Applications			Force gauge		
				Torque gauge		
				Timer		
Mechanical	Small-Bore Connectors for	Resistance to Separation from	ISO 80369-7 Section 6.4	Tensile tester	F1, F2	F
	Liquids and Gases in	Axial Load	ISO 80369-20 Annex F	Load cell		
	Healthcare Applications –			Thermometer/hygrometer		
	Connectors for Intravascular			ISO 80369-7 reference connector		
	or Hypodermic Applications			Force gauge		
				Torque gauge		



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OF TEST	OR PRODUCTS TESTED	PARAMETER TESTED	STANDARD METHOD		E1 E2	OF ACTIVITY
Mechanical	Small-Bore Connectors for	Resistance to Separation from	ISO 80369-7 Section 6.5	I nermometer/nygrometer	F1, F2	F
	Liquids and Gases in	Unscrewing	ISO 80369-20 Annex G	ISO 80369-7 reference connector		
	Healthcare Applications –			Force gauge		
	Connectors for Intravascular			Torque gauge		
	or Hypodermic Applications			Timer		
Mechanical	Small-Bore Connectors for	Resistance to Overriding	ISO 80369-7 Section 6.6	Thermometer/hygrometer	F1, F2	F
	Liquids and Gases in		ISO 80369-20 Annex H	ISO 80369-7 reference connector		
	Healthcare Applications –			Force gauge		
	Connectors for Intravascular			Torque gauge		
	or Hypodermic Applications			Timer		
Mechanical	Small-Bore Connectors for	Leakage by Pressure Decay	ISO 80369-3 Section	Leak tester	F1, F2	F
	Liquids and Gases in		6.1.2	Thermometer/hygrometer		
	Healthcare Applications –		ISO 80369-20 Annex B	ISO 80369-3 reference connector		
	Connectors for Enteral			Force gauge		
	Applications			Torque gauge		
Mechanical	Small-Bore Connectors for	Positive Pressure Liquid	ISO 80369-3 Section	Hydraulic pressure tester	F1, F2	F
	Liquids and Gases in	Leakage	6.1.3	Thermometer/hygrometer		
	Healthcare Applications –		ISO 80369-20 Annex C	ISO 80369-3 reference connector		
	Connectors for Enteral			Force gauge		
	Applications			Torque gauge		
Mechanical	Small-Bore Connectors for	Stress Cracking	ISO 80369-3 Section 6.2	Hydraulic pressure tester or Leak	F1, F2	F
	Liquids and Gases in		ISO 80369-20 Annex E	tester		
	Healthcare Applications –			Thermometer/hygrometer		
	Connectors for Enteral			ISO 80369-3 reference connector		
	Applications			Force gauge		
				Torque gauge		
				Timer		
Mechanical	Small-Bore Connectors for	Resistance to Separation from	ISO 80369-3 Section 6.3	Tensile Tester	F1, F2	F
	Liquids and Gases in	Axial Load	ISO 80369-20 Annex F	Load cell	-	
	Healthcare Applications –			Thermometer/hygrometer		
	Connectors for Enteral			ISO 80369-3 reference connector		
	Applications			Force gauge, Torque gauge		



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FIELD	ITEMS, MATERIALS,	COMPONENT, CHARACTERISTIC,	SPECIFICATION OR	TECHNOLOGY OR TECHNIQUE USED	FLEX CODE	LOCATION
OF TEST	OR PRODUCTS TESTED	PARAMETER TESTED	STANDARD METHOD		E1 E2	OF ACTIVITY
Mechanical	Small-Bore Connectors for	Resistance to Separation from	ISO 80369-3 Section 6.4	I hermometer/nygrometer	F1, F2	F
	Liquids and Gases in	Unscrewing	ISO 80369-20 Annex G	ISO 80369-3 reference connector		
	Healthcare Applications –			Force gauge		
	Connectors for Enteral			Torque gauge		
	Applications			Timer		
Mechanical	Small-Bore Connectors for	Resistance to Overriding	ISO 80369-3 Section 6.5	Thermometer/hygrometer	F1, F2	F
	Liquids and Gases in		ISO 80369-20 Annex H	ISO 80369-3 reference connector		
	Healthcare Applications –			Force gauge		
	Connectors for Enteral			Torque gauge		
	Applications			Timer		
Mechanical	Small-Bore Connectors for	Disconnection by Unscrewing	ISO 80369-3 Section 6.6	Thermometer/hygrometer	F1, F2	F
	Liquids and Gases in		ISO 80369-20 Annex I	ISO 80369-3 reference connector		
	Healthcare Applications –			Force gauge		
	Connectors for Enteral			Torque gauge		
	Applications			Timer		
Mechanical	Intravascular Catheters –	Corrosion Resistance	ISO 10555-1 Section 4.8	Balance/scale	F1, F2	F
	Sterile and Single-Use		and Annex A	Water bath		
	Catheters			Hot plate		
				Timer		
				Thermocouple/thermometer		
Mechanical	Intravascular Catheters –	Peak Tensile Force	ISO 10555-1 Section 4.9	Tensile tester	F1, F2	F
	Sterile and Single-Use		and Annex B	Load cell		
	Catheters			Timer		
				Calipers		
				Water bath		
				Thermocouple		
Mechanical	Intravascular Catheters –	Freedom from Leakage During	ISO 10555-1 Section	Hydraulic pressure tester	F1, F2	F
	Sterile and Single-Use	Pressurization	4.10 and Annex C	Thermocouple	,	
	Catheters			1		
Mechanical	Intravascular Catheters –	Freedom from-Leakage During	ISO 10555-1 Section	Thermocouple	F1, F2	F
	Sterile and Single-Use	Aspiration	4.11 and Annex D	Timer	,	
	Catheters	*				



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FIELD	ITEMS, MATERIALS,	COMPONENT, CHARACTERISTIC,	SPECIFICATION OR	TECHNOLOGY OR TECHNIQUE USED	FLEX CODE	LOCATION
OF TEST	OR PRODUCTS TESTED	PARAMETER TESTED	STANDARD METHOD			OF ACTIVITY
Mechanical	Intravascular Catheters –	Power Injection	ISO 10555-1 Section	Power injector	F1, F2	F
	Sterile and Single-Use		4.14 (Method B) and	Pressure gauge		
	Catheters		Annex F and G	Water bath		
				Viscometer		
				Thermocouple		
				Timer		
Mechanical	Sterile Hypodermic	Dead Space	ISO 7886-1 Section 13.1	Balance/scale	F1, F2	F
	Syringes for Single Use		and Annex C		,	
Mechanical	Sterile Hypodermic	Freedom from Liquid Leakage	ISO 7886-1 Section 13.2	Thermometer/hygrometer	F1, F2	F
	Syringes for Single Use	1 0	and Annex D	Weights		
			ISO 7886-2 Section 14.2	Pressure gauge		
				Timer		
				Thermocouple		
Mechanical	Sterile Hypodermic	Freedom from Air Leakage	ISO 7886-1 Section 13.2	Thermometer/hygrometer	F1, F2	F
	Svringes for Single Use		and Annex B	Timer	,	
	, 6 6		ISO 7886-2 Section 14.2	Vacuum pump/gauge		
				Thermocouple		
Mechanical	Medical Devices	Radiopacity	ASTM F640	C-arm	F1, F2	F
		1		ruler	,	
Dimensional	Small-bore Connectors for	Dimensional Requirements	ISO 80369-7 Section 5	Thermometer/hygrometer	F1, F2	F
	Liquids and Gases in	1	and Annex B	Keyence		
	Healthcare Applications –			CMM		
	Connectors for Intravascular					
	or Hypodermic Applications					
Dimensional	Small-bore Connectors for	Dimensional Requirements	ISO 80369-3 Section 5	Thermometer/hygrometer	F1, F2	F
	Liquids and Gases in	1	and Annex B	Kevence	,	
	Healthcare Applications –			CMM		
	Connectors for Enteral					
	Applications					



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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

