

PERRY JOHNSON LABORATORY ACCREDITATION, INC.

Certificate of Accreditation

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

Medical Murray

400 North Rand Rd, North Barrington, IL 60010

(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 and Dimensional 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:

June 17, 2021

June 17, 2021

August 31, 2023

Revision Date:

Accreditation No.:

Certificate No.:

April 5, 2022

108231

L21-390-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



Issue: 6/2021



Certificate of Accreditation: Supplement

Medical Murray 400 North Rand Rd, North Barrington, IL 60010 Contact Name: Ken Carlson Phone: 847-847-3700

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
Mechanical ^F	Small-Bore Connectors for Liquids and Gases in Healthcare Applications – Connectors for Intravascular or Hypodermic Applications	Leakage by Pressure Decay	ISO 80369-7 Section 6.1.2	N/A
		(1)	ISO 80369-20 Annex B	-
		Positive Pressure Liquid	ISO 80369-7 Section 6.1.3	
		Leakage (2)	ISO 80369-20 Annex C	
		Sub-atmospheric Pressure	ISO 80369-7 Section 6.2	
		Air Leakage (3)	ISO 80369-20 Annex D	
		Stress Cracking (4)	ISO 80369-7 Section 6.3	
			ISO 80369-20 Annex E	
		Resistance to Separation	ISO 80369-7 Section 6.4	
		from Axial Load (5)	ISO 80369-20 Annex F	
		Resistance to Separation	ISO 80369-7 Section 6.5	
		from Unscrewing (6)	ISO 80369-20 Annex G	
		Resistance to Overriding (7)	ISO 80369-7 Section 6.6	
			ISO 80369-20 Annex H	
	Small-Bore	Leakage by Pressure Decay	ISO 80369-3 Section 6.1.2	
	Connectors for	(8)	ISO 80369-20 Annex B	
	Liquids and Gases	Positive Pressure Liquid	ISO 80369-3 Section 6.1.3	
	in Healthcare	Leakage (9)	ISO 80369-20 Annex C	
	Applications – Connectors for Enteral Applications	Stress Cracking (10)	ISO 80369-3 Section 6.2	
			ISO 80369-20 Annex E	
		Resistance to Separation	ISO 80369-3 Section 6.3	
		from Axial Load (11)	ISO 80369-20 Annex F	
		Resistance to Separation	ISO 80369-3 Section 6.4	
		from Unscrewing (12)	ISO 80369-20 Annex G	
		Resistance to Overriding	ISO 80369-3 Section 6.5	
		(13)	ISO 80369-20 Annex H	
		Disconnection by	ISO 80369-3 Section 6.6	
		Unscrewing (14)	ISO 80369-20 Annex I	
	Intravascular	Corrosion Resistance (15)	ISO 10555-1 Section 4.5	
	Catheters – Sterile		and Annex A	
	and Single-Use Catheters	Peak Tensile Force (16)	ISO 10555-1 Section 4.6	
			and Annex B	
		Freedom from Liquid	ISO 10555-1 Section 4.7.1	
		Leakage (17)	and Annex C	
		Freedom from Air Leakage	ISO 10555-1 Section 4.7.2	
		(18)	and Annex D	
		Flowrate (19)	ISO 10555-1 Section 4.9	
			and Annex E	
		Power Injection (20)	ISO 10555-1 Section 4.10	
			and Annex F and G	





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Mechanical ^F	Sterile Hypodermic Syringes for Single	Dead Space (21)	ISO 7886-1 Section 13.1 and Annex C	N/A
	Use	Freedom from Liquid	ISO 7886-1 Section 13.2	
		Leakage (22)	and Annex D	
			ISO 7886-2 Section 14.2	
		Freedom from Air	ISO 7886-1 Section 13.2	
		Leakage (23)	and Annex B	
			ISO 7886-2 Section 14.2	
	Medical Devices	Radiopacity (24)	ASTM F640	
Dimensional ^F	Small-bore Connectors	Dimensional Requirements	ISO 80369-7 Section 5 and	
	for Liquids and Gases	(25)	Annex B	
	in Healthcare			
	Applications –			
	Connectors for			
	Intravascular or			
	Hypodermic			
	Applications			
	Small-bore Connectors	Dimensional Requirements	ISO 80369-3 Section 5 and	
	for Liquids and Gases	(26)	Annex B	
	in Healthcare			
	Applications –			
	Connectors for Enteral			
	Applications			

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