

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:

Lacy Szuszer

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, 2021June 17, 2021August 31, 2023Accreditation No.:Certificate No.:108231L21-390

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>



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
Mechanical ^F	Small-Bore Connectors for	Leakage by Pressure	ISO 80369-7 Section 6.1.2
	Liquids and Gases in	Decay (1)	ISO 80369-20 Annex B
	Healthcare Applications –	Positive Pressure Liquid	ISO 80369-7 Section 6.1.3
	Connectors for	Leakage (2)	ISO 80369-20 Annex C
	Intravascular or	Sub-atmospheric Pressure	ISO 80369-7 Section 6.2
	Hypodermic Applications	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	ISO 80369-7 Section 6.6
		(7)	ISO 80369-20 Annex H
	Small-Bore Connectors for	Leakage by Pressure	ISO 80369-3 Section 6.1.2
	Liquids and Gases in	Decay (8)	ISO 80369-20 Annex B
	Healthcare Applications –	Positive Pressure Liquid	ISO 80369-3 Section 6.1.3
	Connectors for Enteral	Leakage (9)	ISO 80369-20 Annex C
	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 Catheters –	Corrosion Resistance (15)	ISO 10555-1 Section 4.5
	Sterile and Single-Use		and Annex A
	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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FIELD OF TEST	ITEMS, MATERIALS OR PRODUCTS TESTED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED
Mechanical ^F	Sterile Hypodermic Syringes for Single Use	Dead Space (21)	ISO 7886-1 Section 13.1 and Annex C
		Freedom from Liquid Leakage (22)	ISO 7886-1 Section 13.2 and Annex D ISO 7886-2 Section 14.2
		Freedom from Air Leakage (23)	ISO 7886-1 Section 13.2 and Annex B ISO 7886-2 Section 14.2
	Medical Devices	Radiopacity (24)	ASTM F640
	Medical Packaging	Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test) (25)	ASTM F2096
	Flexible Barrier Materials	Seal Strength of Flexible Barrier Materials (26)	ASTM F88/F88M
Dimensional ^F	Small-bore Connectors for Liquids and Gases in Healthcare Applications – Connectors for Intravascular or Hypodermic Applications	Dimensional Requirements (27)	ISO 80369-7 Section 5 and Annex B
	Small-bore Connectors for Liquids and Gases in Healthcare Applications – Connectors for Enteral Applications	Dimensional Requirements (28)	ISO 80369-3 Section 5 and Annex B

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