



CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

iuvo BioScience, LLC
7500 West Henrietta Rd.
Rush, NY 14543

Fulfills the requirements of

ISO/IEC 17025:2017

In the field of

TESTING

This certificate is valid only when accompanied by a current scope of accreditation document.
The current scope of accreditation can be verified at www.anab.org.

A handwritten signature in black ink, appearing to read 'R. Douglas Leonard Jr.', is positioned above a horizontal line.

R. Douglas Leonard Jr., VP, PILR SBU

Expiry Date: 24 August 2022
Certificate Number: AT-2068



This laboratory 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 (refer to joint ISO-ILAC-IAF Communiqué dated April 2017).

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

iuvo BioScience, LLC

7500 West Henrietta Rd.
Rush, NY 14543
Nancy Rakiewicz
585-533-1672

TESTING

Valid to: **August 24, 2022**

Certificate Number: **AT-2068**

Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Cytotoxic Reactivity	CYT-3 based on USP <87> and ISO 10993-5:2009	Textiles, Medical Devices	CO2 incubator, Microscope
Biological Reactivity	CYT-2 based on USP <87>, <381>, <1031> and ISO 10993-5:2009	Textiles, Medical Devices	CO2 incubator, Microscope
Bacterial Endotoxins (LAL)	PYT-10 based on ANSI/AAMI ST72:2011	Medical Devices, Pharmaceuticals, Biologics	Microplate Reader
MEM Elution	CYT-1 based on USP <87>, ISO 10993-5:2009, ANSI/AAMI/ISO 10993-12:2012.	Medical Devices, Pharmaceuticals, Biologics	ISO Class 5 Hoods Microscope Incubators
Acute Systemic Toxicity	CLE-2 based on <USP> 88, 2.12 ANSI/AAMI/ISO 10993-11:2006, JP XVI, <7.03>, JP XVI, Supplement II, <7.03>	Medical Devices	
Intracutaneous	CLE-4 based on <USP> 88 CLE-5 based on <ISO 10993-10:2010>	Medical Devices, Pharmaceuticals, Biologics	
Sensitization	SST-1 based on ISO 10993-10:2010(E)	Medical Devices, Pharmaceuticals, Biologics	
Muscle Implantation	CLE 6, CLE-8 based on <USP> 88, ANSI/AAMI/ISO 10993-6:2007	Medical Devices, Pharmaceuticals	

Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Buehler Patch Sensitization Test	SST-3 based on ISO 10993-10:2010	Medical Devices, Pharmaceuticals	Scale Incubator
Ocular Irritation Test	CLE-7 based on <ISO 10993-10:2010>	Medical Devices, Pharmaceuticals	Slit Lamp Scale Incubator
General Safety Test/Abnormal Toxicity Test	MDT-1, MDT-2 based on USP <88>, EP <2.6.9>	Medical Devices, Pharmaceuticals	Scale
Rabbit Pyrogen Test	PYT-1, PYT-2, PYT-9 based on USP <151>, EP <2.6.8>, JP <4.04>	Medical Devices, Pharmaceuticals	Scale Incubator Temperature Probe
Hemolysis Test	BCT-2 based on ASTM 756	Medical Devices, Pharmaceuticals	Spectrophotometer Scale Incubator
Primary Skin Irritation Test	SST-2 based on <ISO 10993-10:2010>	Medical Devices, Pharmaceuticals	Scale Incubator

Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Bioburden	M-8 based on ANSI/AMMI/ISO 11737-1:2006.	Textiles, Medical Devices, Tissues, Pharmaceuticals	ISO Class 5 Hoods Incubators
Biological Indicator Sterility	S-2 based on ANSI/AAMI/ISO 11737-2:2009.	BI's, PCD's	Sterility Suite Class 5 Hoods Incubator
Product Sterility	S-2 based on USP <71>, ANSI/AAMI/ISO 11737-2:2009, 1137-01 and -02, ANSI/AAMI/ISO 11137-2:2013, AAMI TIR33:2005	Medical Devices, Pharmaceuticals, Biologics, Tissues	Sterility Suite Class 5 Hoods Incubator
Bacteriostasis / Fungistasis	M-12, based on USP <71>	Medical Devices, Pharmaceuticals, Biologics, Tissues	Incubator, Membrane Filtration
Population Determination	M-6 based on USP <55>	BI's	Incubator, Colony Counter
Heterotrophic Plate Count (Water) Test	M-1 based on USP <1231>	Water	Incubator. Colony Counter

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Ethylene Oxide (EO) Residual Analysis	CA-2 based on ANSI/AAMI/ISO 10993-7:2008/(R)2012	Medical Devices	Gas Chromatograph, FID

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-2068.



R. Douglas Leonard Jr., VP, PILR SBU

