



# 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](http://www.anab.org).

Jason Stine, Vice President

Expiry Date: 24 August 2024

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, 2024**

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	Textiles, Medical Devices	Incubator ISO Class 5 Hood CO2 incubator, Microscope
Biological Reactivity	CYT-2 based on USP <87>, <381>, <1031> and ISO 10993-5	Textiles, Medical Devices	Incubator ISO Class 5 Hood CO2 incubator, Microscope
Bacterial Endotoxins (LAL)	PYT-10 based on ANSI/AAMI ST72	Medical Devices, Pharmaceuticals, Biologics	Incubator ISO Class 5 Hood Microplate Reader
MEM Elution	CYT-1 based on USP <87>, ISO 10993-5, ANSI/AAMI/ISO 10993-12.	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, JP <7.03>	Medical Devices	Balance Incubator
Intracutaneous	CLE-4 based on USP< 88> CLE-5 based on ISO 10993-10	Medical Devices, Pharmaceuticals, Biologics	Balance Incubator
Sensitization	SST-1 based on ISO 10993-10	Medical Devices, Pharmaceuticals, Biologics	Balance Incubator

### Biological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Muscle Implantation	CLE 6, CLE-8 based on USP <88>, ANSI/AAMI/ISO 10993-6	Medical Devices, Pharmaceuticals	Anesthesia Machine Calipers
Buehler Patch Sensitization Test	SST-3 based on ISO 10993-10	Medical Devices, Pharmaceuticals	Balance Incubator
Ocular Irritation Test	CLE-7 based on ISO 10993-10	Medical Devices, Pharmaceuticals	Slit Lamp Scale Incubator
General Safety Test	MDT-1 based on USP <88>	Medical Devices, Pharmaceuticals	Scale
Rabbit Pyrogen Test	PYT-1, PYT-2 based on USP <151>, EP <2.6.8>,	Medical Devices, Pharmaceuticals	Scale Incubator Temperature Probe
Hemolysis Test	BCT-2 based on ASTM 756	Medical Devices, Pharmaceuticals	Spectrophotometer Scale Incubator Centrifuge
Primary Skin Irritation Test	SST-2 based on ISO 10993-10	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 M-9 based on ANSI/AAMI/ISO 11737-1	Textiles, Medical Devices, Tissues, Pharmaceuticals	ISO Class 5 Hoods Incubators
Biological Indicator Sterility	S-2 based on ANSI/AAMI/ISO 11737-2	BI's, PCD's	Sterility Suite ISO Class 5 Hoods Incubator
Product Sterility	S-2 based on USP <71>, ANSI/AAMI/ISO 11737-2, ANSI/AAMI/ISO 11137-1 and 11137-2, AAMI TIR33	Medical Devices, Pharmaceuticals, Biologics, Tissues	Sterility Suite ISO Class 5 Hoods Incubator
Bacteriostasis / Fungistasis	M-12, based on USP <71>	Medical Devices, Pharmaceuticals, Biologics, Tissues	Incubator

**Microbiological**

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
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	Medical Devices	Gas Chromatograph, FID Balance Incubator

Note:

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



Jason Stine, Vice President

