



**SMITHERS**  
QUALITY ASSESSMENTS

## CERTIFICATE OF APPROVAL

This is to Certify that the Quality Management System of:

**Tessy Medical Products, LLC**  
4900 Technology Park Boulevard  
Auburn, NY 13021

(Page 1 of 2; see Appendix)

has been assessed and approved by Smithers Quality Assessments, Inc., to the following quality management system standards and requirements:

### **ISO 13485:2016 without Design**

The Quality Management System is Applicable to:

Contract injection molding and assembly of precision plastic components, compounding of reagents, and final kit assembly of diagnostic test kits.

Approval Certificate Number: 21.105.1

Original Approval: April 15, 2021

Current Certificate: February 11, 2022

Certificate Expires: February 10, 2025



*The use of the accreditation mark indicates accreditation in respect of those activities covered by the above certificate number.*

  
on behalf of SQA - J. Michael Hochschwender, CEO

The approval is subject to the company maintaining its system to the required standards which will be monitored by Smithers Quality Assessments, Inc., 121 S. Main St. Suite 300, Akron, Ohio 44308, USA



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**APPENDIX A**  
TO THE CERTIFICATE  
OF REGISTRATION NO.: 21.105.1

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**SMITHERS QUALITY ASSESSMENTS, INC.**

**Site:**

Tessy Medical Products, LLC  
4900 Technology Park Boulevard  
Auburn, NY 13021

Scope of activities: Contract injection molding and assembly of precision plastic components, compounding of reagents, and final kit assembly of diagnostic test kits.

The above site is certified by Smithers Quality Assessments, Inc. with regard to ISO 13485:2016 without Design. The following locations are included utilizing a Multi-site (with no Sampling) approach.

**Location(s):**

Tessy Medical LLC  
360 Grant Avenue  
Auburn, NY 13021

Scope of activities: Contract compounding of controls, of diagnostic test kits.

Applicable Standard: ISO 13485:2016 without Design

*This appendix applies only to those sites listed above. As other sites are assessed and approved, or as sites already approved are removed from active services, this appendix will be amended to show the current status. Sites not listed on this appendix shall not be viewed as approved.*

