



**SMITHERS**  
QUALITY ASSESSMENTS

## CERTIFICATE OF APPROVAL

This is to Certify that the Quality Management System of:

**Tessy Plastics Corporation**

700 Visions Drive

Skaneateles, NY 13152, USA

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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, assembly of precision plastic components, and of finished medical devices serving global customers.

Approval Certificate Number: 10.050.2

Original Approval: February 19, 2010

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 REGISTRATION OF  
REGISTRATION NO.: 10.050.2

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**SMITHERS QUALITY ASSESSMENTS, INC.**

Tessy Plastics Corporation, 700 Visions Drive, Skaneateles, NY 13152, USA  
Scope of activities: Contract injection molding, assembly of precision plastic components, and of finished medical devices serving global customers.

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 Plastics Corporation, 7474 State Fair Boulevard, Baldwinsville, NY 13027, USA  
Scope of activities: Contract injection molding and assembly of precision plastic components serving global customers.

Tessy Plastics Corporation, 488 State Route 5 West, Elbridge, NY 13060, USA  
Scope of activities: Contract injection molding, assembly of precision plastic components, electromechanical components and finished medical devices serving global customers.

Tessy Plastics Corporation, 4900 Technology Park Boulevard, Auburn, NY 13021, USA  
Scope of activities: Contract injection molding and assembly of precision plastic components, compounding and final assembly of medical and diagnostic devices, serving global customers.

**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.



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**SMITHERS QUALITY ASSESSMENTS, INC.**

Tessy Plastics Corporation - Webster Warehouse, 1500 Mitcheldean Drive, Building 214, Webster, NY 14580, USA

Scope of activities: Warehousing out of use equipment and raw materials.

**Applicable Standard: ISO 13485:2016 without Design**

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Sites not listed on this appendix shall not be viewed as approved.

