## **TUV**USA

## Certificate

Management system as per

ISO 13485:2016

The Certification Body TUV USA, Inc. hereby confirms as a result of the audit, assessment, and certification decision according to ISO/IEC 17021-1:2015, that the organization

Wise Plastics Technologies 3810 Stern Avenue Saint Charles, Illinois 60174 United States of America

With "Additional Sites" according to the annex

Operates a management system in accordance with the requirements of ISO 13485:2016 and will be assessed for conformity within the 3-year term of validity of the certificate

Scope

Manufacture of custom injection molded components for medical devices

Contract manufacture (including assembly and finishing) of components for medical devices

Design and development of injection mold for customer specific engineered medical products

Certificate Registration No. 25-1610-Q Project No. 25-4126 RC 

 Issue Date:
 2025-05-13

 Reissue Date:
 2025-04-19

 Expiry Date:
 2028-05-12

 Initial Certification Date:
 2016-05-26

Salem, NH; 2025-04-19, Edition 1

Certification Body TUV USA, Inc.

TUV USA, Inc. 215 Main Street, Salem, NH 03079 United States of America www.tuv-nord.com/us TÜV ®



The validity of this certificate may be obtained by contacting TUV USA at: +1 (603) 870-8023 (option 1) or via Email: medicalusa@tuv-nord.com

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TUV USA, Inc. is accredited by ANAB, an MLA Signatory

## TUVUSA

## Annex

to Certificate Registration No. 25-1610-Q

ISO 13485:2016

**End of the List** 

Wise Plastics Technologies 3810 Stern Avenue Saint Charles, Illinois 60174 United States of America

Validity of Annex depends on the validity of the main certificate.

Certificate Registration No.	Location	Scope
25-1610-Q	Wise Plastics Technologies 3810 Stern Avenue Saint Charles, Illinois 60174 United States of America	Headquarters Top management, DCC, engineering, HR, quality assurance, warehousing, receiving
25-1610-Q -001	Wise Plastics Technologies 1601 & 1701 West Hawthorne Lane West Chicago, Illinois 60186 United States of America	Assembly, warehousing, shipping, purchasing, sales

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