

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 St. Charles, Illinois 60174 USA

with the locations according to the annex

operates a management system in accordance with the requirements of ISO 13485:2016 for Medical Devices-Quality Management Systems-Requirements for Regulatory Purposes and will be assessed for conformity within the 3 year term of validity of the certificate.

Scope

Manufacture and Assembly for Injection Molded Products and Plastic Injection Molded Components for Medical Devices

Design and Development of Injection Mold for Customer Specific Products

Certificate Registration No. 19-1626-Q Audit Report No. 21-3695 SA1-SPA

Certification Body at TUV USA, Inc.

Valid from 2024-01-25 Valid until 2025-05-12 Initial certification 2017-02-15

Salem, NH 2024-01-25 ed. 5

TUV USA, Inc.

215 Main Street, Salem, NH 03079, USA

www.tuv-nord.com/us





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ANNEX

to Certificate Registration No. 19-1626-Q ISO 13485 : 2016

Wise Plastics Technologies 3810 Stern Avenue St. Charles, Illinois 60174 USA

Location

Wise Plastics Technologies 3810 Stern Avenue St. Charles, Illinois 60174 USA

Wise Plastics Technologies 1601 & 1701 West Hawthorne Lane West Chicago, Illinois 60186 USA

End of the List

Scope

Top Management, DCC, Engineering, HR, Quality Assurance, Purchasing, Sales, Warehouse, Receiving

Assembly, Warehouse, Shipping

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