Certificate

acc. to ISO 13485:2016

Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

Certificate Registration No.: 19-1626-Q

TUV USA, Inc. hereby certifies that the quality management system of the company mentioned below is in conformance with ISO 13485:2016 for Medical Devices-Quality Management Systems-Requirements for Regulatory Purposes.

Wise Plastics Technologies
3810 Stern Ave.
St. Charles, IL 60174, USA

Additional sites covered by QM System: See Annex 1

Scope:

The Manufacture and Value Added Process Design of Engineered Injection Molded Products and Assemblies

The validity of this certification document can be obtained by contacting the TUV USA, Inc. Office.

TUV USA, Inc. (a Member of the TÜV NORD Group)
215 Main Street, Suite 1, Salem, NH 03079, USA
Tel: 001-603-870-8023, Fax: 001-603-870-8026, Email: medical-usa@tuv-nord.com

Audit Report Reference No.: 21-3965 RC
Initial Certification Date: 2017-02-15
Current Cycle Start Date: 2022-05-13

Effective Date:
2022-05-13 / ed. 4

Valid Until:
2025-05-12

Bradley Chen
Vice President – Medical, Americas
Medical Products Division
TUV USA, Inc.

Certificate Registration No. : **19-1626-Q / ed. 4**
Company Name: ***Wise Plastics Technologies***
Central Office Address: ***3810 Stern Ave., St. Charles, IL 60174, USA***

Additional Site(s) covered by the QM System:

Location	Scope of Certification
Wise Plastics Technologies 3810 Stern Ave. St. Charles, IL 60174, USA	Top Management, DCC, Engineering, HR, Quality Assurance, Purchasing, Sales, Warehouse, Receiving
Wise Plastics Technologies 1601 & 1701 W. Hawthorne Lane West Chicago, IL 60186, USA	Assembly, Warehouse, Shipping

---End of list---

The validity of this certification document can be obtained by contacting the TUV USA, Inc. Office.

TUV USA, Inc. (a Member of the TÜV NORD Group)
215 Main Street, Suite 1, Salem, NH 03079, USA
Tel: 001-603-870-8023, Fax: 001-603-870-8026, Email: medical-usa@tuv-nord.com

Audit Report Reference No.: **21-3965 RC**
Initial Certification Date: **2017-02-15**
Current Cycle Start Date: **2022-05-13**

Effective Date:
2022-05-13 / ed. 4

Valid Until:
2025-05-12

Bradley Chen
Vice President – Medical, Americas
Medical Products Division
TUV USA, Inc.