

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

Fabriform LLC (dba The Fi Company – Seattle)
3300 Airport Way South
Seattle, Washington 98134
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 Medical Device Components Through Reaction Injection Molding, Thermoforming, and Custom Fabrication Processes

Certificate Registration No. 25-1612-Q
Project No. 25-4122 RC

Issue Date: 2025-05-19
Reissue Date: --
Expiry Date: 2028-05-18
Initial Certification Date: 2023-05-19

Salem, NH; 2025-06-02, Edition 1


Certification Body TUV USA, Inc.

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

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