

Certificate

acc. to ISO 13485:2016

Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

Certificate Registration No.: 19-1618-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.

Hanson Medical, Inc. 25960 Ohio Avenue NE, Suite 200 Kingston, WA 98346, USA

Additional sites covered by QM System: See Annex I

Scope:

Design, Development, Manufacture, and Distribution of Silicone Facial and Body Implants, Silicone Devices, Accessories, and Topical Scar Gel Products

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.: 19-3711 SPA
Certificate Initial Issue Date: 2019-02-28
Current Cycle Start Date: 2020-07-09
Certificate Revised Date: 2021-02-15

Effective Date: 2021-02-15 / ed. 5

Valid Until: 2023-07-08

Bradley Chen

Vice President – Medical, Americas Medical Products Division

TUV USA, Inc.

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(Annex 1 must be displayed with the main certificate)

Certificate Registration No.

: 19-1618-Q / ed. 5

Company Name:

Hanson Medical, Inc.

Central Office Address:

25960 Ohio Avenue NE, Suite 200 Kingston, WA 98346, USA



Additional Site(s) covered by the QM System:

Location

Scope of Certification

Hanson Medical, Inc. 25960 Ohio Avenue NE Suite 200 Kingston, WA 98346, USA Administration and Sales

Hanson Medical, Inc. 3527 Combine Street Paso Robles, CA 93446, USA Design, Development, Manufacture, and Distribution of Silicone Facial and Body Implants, Silicone Devices, Accessories, and Topical Scar Gel Products

---End of list---

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