

Certificate

acc. to ISO 13485:2016

Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

Certificate Registration No.: 19-1602-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.

GCX Corporation 3875 Cypress Drive Petaluma, CA 94954, USA

Additional sites covered by QM System: See Annex 1

Scope:

Design, Manufacturing, and Distribution of Mounting Equipment for Medical Devices

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.: 20-3874 SA2
Certificate Initial Issue Date: 2019-01-17
Current Cycle Start Date: 2019-01-17
Certificate Revised Date: 2021-05-11

Effective Date: 2021-05-11 / ed. 3

Valid Until: 2022-01-16

Bradley Chen

Vice President – Medical, Americas Medical Products Division

Wedical Products Division

TUV USA, Inc.

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(Annex 1 MUST be displayed with the main certificate)

Certificate Registration No.: 19-1602-Q / ed. 3

Company Name:

GCX Corporation

Central Office Address:

3875 Cypress Drive, Petaluma, CA 94954, USA



Additional Site(s) covered by the QM System:

Location

Site 01

GCX Corporation 3905 Cypress Drive Petaluma, CA 94954, USA

Site 02

GCX Corporation 26 & 28 Spur Drive El Paso, TX 79906, USA

Site 03

GCX Corporation No. 42 Wogong 5th Road Wugu District, New Taipei City 248 Taiwan, R.O.C.

Scope of Certification

Design, Manufacturing, Distribution, and Testing of Mounting Equipment for Medical Devices

Design, Manufacturing, and Distribution of Mounting Equipment for **Medical Devices**

Manufacturing and Distribution of Mounting Equipment for Medical Devices

---End of list---

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