TUVUSA

Certificate

acc. to ISO 13485:2016

Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

Certificate Registration No.: 18-1632-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.



Nextek, Inc. 201 Next Technology Drive Madison, Alabama 35758, USA

Additional sites covered by QM System: See Annex 1

Scope:

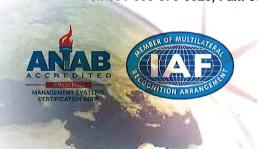
Contract Manufacturing, Assembly, and Testing of Printed Circuit Assemblies for Electro-Medical Therapeutic Devices

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.: 23-4036 RC Initial Certification Date: 2017-08-18 Current Cycle Start Date: 2023-08-18

Effective Date: 2023-08-18 / ed. 6

Valid Until: 2026-08-17

Bradley Chen
Vice President – Medical, Americas
Medical Products Division

TUV USA, Inc.

Annex 1, page 1 of 1

(Annex 1 MUST be displayed with the main certificate)



Certificate Registration No.: 18-1632-Q / ed. 6

Company Name:

Nextek, Inc.

Central Office Address:

201 Next Technology Drive Madison, Alabama 35758, USA

Additional Sites covered by the QM System:

Location

Headquarters

Nextek, Inc. 201 Next Technology Drive Madison, Alabama 35758, USA

Site 01

Nextek, Inc. 100 Research Boulevard Madison, Alabama 35758, USA

Scope of Certification

Contract Manufacturing, Assembly, and Testing of Printed Circuit Assemblies for Electro-Medical Therapeutic Devices

Purchasing, Sales, Marketing, Document Control, Project Management

---End of list---

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