



CERTIFICATE



This is to certify that

Benchmark Electronics, Inc.

Minnesota Division

4065 Theurer Boulevard
Winona, MN 55987
United States of America

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope:

Contract Design of active medical devices and software according to customer specifications.

Contract Manufacturing of Active, Non-Implantable Medical Devices, including peritoneal dialysis machines for home use, ethylene oxide gas sterilizers for general hospital use, laser vein location devices, programmers for active implantable stimulation devices, power supply devices for embolization coil detachment systems, patient signal registration and processing units, continuous blood pressure and heart rate monitors, pain management pulse generators, printed circuit board assemblies for medical devices according to customer specifications, hypo-/hyperthermia device for patient temperature regulation, monitor stands for operating rooms, console devices used to control surgical power tools and oblation surgical tools, EKG Monitoring Device, Sterilization and Microbiological Indicators, Radiofrequency Lesion Generator, Ultrasonic Surgical Instrument, Electrosurgical, Cutting & Coagulation & Accessories, Programmable Diagnostic Computer, Wearable Automated External Defibrillator, Medical Device Data System, External Pulse Generator, Electrocardiograph, Ambulatory (without analysis), Focused Ultrasound for Tissue Heat or Mechanical Cellular Disruption, Illuminator System for Blood Products, Non-invasive Transdermal Fluorescence Detection, Quantitative Detection of Acetylcholinesterase Activity.

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 13485 : 2016

Certificate registration no.	10011903 MP2016
Date of original certification	2012-11-06
Date of revision	2024-12-19
Date of certification	2023-12-16
Valid until	2027-02-01



DQS IS A MEMBER OF



DQS Inc.

David Tellez
Managing Director

Accredited Body: DQS Inc., 1500 McConnor Parkway, Suite 400, Schaumburg, IL 60173 USA
The validity of the certification can only be verified by the QR-code.



Annex to certificate Registration No. 10011903 MP2016

Benchmark Electronics, Inc.

Minnesota Division

4065 Theurer Boulevard
Winona, MN 55987
United States of America

Location

10011903
Benchmark Electronics Inc.
Minnesota Division
4065 Theurer Boulevard
Winona, MN 55987
United States of America

10011920
Benchmark Electronics, Inc.
Minnesota Division
3535 Technology Drive
Rochester, MN 55901
United States of America

10011921
Benchmark Electronics Inc.
Minnesota Division
4155 Theurer Blvd.
Winona, MN 55987
United States of America

Scope

Contract Manufacturing of Printed Circuit Board Assemblies according to customer specifications.

Design of active medical devices and software according to customer specifications.
Receiving, Receiving Inspection and Shipping.
Contract Manufacturing of Printed Circuit Board Assemblies and System Integration according to customer specifications, including hypo-/hyperthermia device for patient temperature regulation, monitor stands for operating rooms, console devices used to control surgical power tools and ablation surgical tools, Radiofrequency Lesion Generator, Ultrasonic Surgical Instrument, Electrosurgical, Cutting & Coagulation & Accessories, Illuminator System for Blood Products, Non-invasive Transdermal Fluorescence Detection, Quantitative Detection of Acetylcholinesterase Activity.

Receiving, Receiving Inspection, and Shipping.
Contract Manufacturing of System Integration according to customer specifications, including ethylene oxide gas sterilizers for general hospital use.



Annex to certificate
Registration No. 10011903 MP2016

Benchmark Electronics, Inc.

Minnesota Division

4065 Theurer Boulevard
Winona, MN 55987
United States of America

Location

10011922

Benchmark Electronics Inc.
Minnesota Division
4245 Theurer Blvd.
Winona, MN 55987
United States of America

Scope

Design of active medical devices and software according to customer specifications.
Contract Manufacturing of System Integration according to customer specifications, including peritoneal dialysis machines for home use, , laser vein location devices, programmers for active implantable stimulation devices, power supply devices for embolization coil detachment systems, patient signal registration and processing units, continuous blood pressure and heart rate monitors, pain management pulse generators, printed circuit board assemblies for medical devices according to customer specifications, hypo-/hyperthermia device for patient temperature regulation, EKG Monitoring Device, Sterilization and Microbiological Indicators, Programmable Diagnostic Computer, Wearable Automated External Defibrillator, Medical Device Data System, External Pulse Generator, Electrocardiograph, Ambulatory (without analysis), Focused Ultrasound for Tissue Heat or Mechanical Cellular Disruption.

10011923

Benchmark Electronics, Inc. - Arden Hills
Northpark Corporate Center
8 Pine Tree Drive, Suite #200
Arden Hills, MN 55112
United States of America

Design of active medical devices and software according to customer specifications.

31618440

Benchmark Electronics, Inc.
370 W. 2nd St.
Winona, MN 55987
United States of America

Design of active medical devices and software according to customer specifications.