



America

CERTIFICATE

No. QS2 102541 0002 Rev. 04

Certificate Holder: Datascope Corp.
1300 MacArthur Blvd
Mahwah NJ 07430
USA

Certification Mark:



Scope of Certificate: Design and Development, Production, Service, and Distribution of Intra-Aortic Balloon-Pumps and Accessories: Li-On Battery Packs, Power Supply, Battery Charging Station, Helium Refilling Station with Helium Tank, Helium Tanks, Mounting Plate, Battery Transport and Storage Case, Transport Protective Cover, ECG Cables, ECG Lead Wires, Adapter Cable, Transducer Cables, Interface Cables, and Line Cords; Design and Development of Heart and Lung Machine Therapy Device; Production of Collagen Raw Material for Use in Medical Application

Standard: ISO 13485:2016

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.: 713257587

Effective Date: 2023-02-06

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Page 1 of 2

Date of Issue: 2023-02-22

(Renee Walker)
Director, US Certification Body, MHS



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No. QS2 102541 0002 Rev. 04

Facility(ies): **Datascope Corp.**
1300 MacArthur Blvd, Mahwah NJ 07430, USA

Facility Scopes: Production of Collagen Raw Material
for Use in Medical Application

Facility(ies): **Datascope Corp.**
45 Barbour Pond Drive, Wayne NJ 07470, USA

Facility Scopes: Design and Development, Production, Service, and Distribution of Intra-Aortic Balloon-Pumps and Accessories: Li-On Battery Packs, Power Supply, Battery Charging Station, Helium Refilling Station with Helium Tank, Helium Tanks, Mounting Plate, Battery Transport and Storage Case, Transport Protective Cover, ECG Cables, ECG Lead Wires, Adapter Cable, Transducer Cables, Interface Cables, and Line Cords; Design and Development of Heart and Lung Machine Therapy

Page 2 of 2
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(Renee Walker)
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