



America

# CERTIFICATE

No. QS6 102541 0004 Rev. 03

**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(s):** **ISO 13485:2016**

**Regulatory Authority(ies):** **Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website [www.tuvsud.com/ps-cert](http://www.tuvsud.com/ps-cert)  
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**REPs Facility ID:** **F005103**

**Effective Date:** **2023-02-06**

**Expiry Date:** **2026-02-05**

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Director, US Certification Body, MHS

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**Regulatory Requirements:    Audit/Certification Criteria**

**Australia**

Therapeutic Goods (Medical Devices) Regulations 2002  
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

**Brazil**

- RDC ANVISA n. 16/2013  
- RDC ANVISA n. 23/2012  
- RDC ANVISA n. 67/2009

**Canada**

- Medical Device Regulations – Part 1- SOR 98/282

**Japan**

- MHLW Ministerial Ordinance 169, Article 4 to Article 68  
- PMD Act

**United States**

- 21 CFR Part 803  
- 21 CFR Part 806  
- 21 CFR Part 807 – Subparts A to D  
- 21 CFR Part 820

**Facility(ies):**

Datascope Corp.  
1300 MacArthur Blvd, Mahwah NJ 07430, USA

Datascope Corp.  
45 Barbour Pond Drive, Wayne NJ 07470, USA

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**Datascope Corp.**

1300 MacArthur Blvd, Mahwah NJ 07430, USA

Production of Collagen Raw Material  
for Use in Medical Application  
REPs Facility ID: F005103

**Datascope Corp.**

45 Barbour Pond Drive, Wayne NJ 07470, USA

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