



America

CERTIFICATE

No. QS2 104155 0004 Rev. 02

Certificate Holder: Datascope Corp
15 Law Drive
Fairfield NJ 07004
USA

Certification Mark:



Scope of Certificate: Design and Development, Manufacturing and Distribution of Intra-Aortic Balloon Catheters, Guidewires and Product Accessories (including Insertion Kits, Introducers Sets (Sheath / Dilators), Catheter Extenders and Arrow Pump Adapters) to Provide Counterpulsation Therapy

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.: 713312688

Effective Date: 2024-08-17

Expiry Date: 2027-08-16

Page 1 of 2

Date of Issue: 2024-05-14

(Renee Walker)
Director, US Certification Body, MHS



America

CERTIFICATE

No. QS2 104155 0004 Rev. 02

Facility(ies):

Datascope Corp

15 Law Drive, Fairfield NJ 07004, USA

Facility Scopes:

Manufacturing of Introducer Sets; Final Packaging and Distribution of Intra-Aortic Balloon Catheters, Guidewires and Product Accessories (including Insertion Kits, Introducer Sets (Sheath / Dilators), Catheter Extenders and Arrow Pump Adapters) to Provide Counterpulsation Therapy

Facility(ies):

Datascope Corp.

45 Barbour Pond Drive, Wayne NJ 07470, USA

Facility Scopes:

Design and Development, Manufacturing, Sterile Packaging and Testing of Intra-Aortic Balloon Catheters, Guidewires and Product Accessories (including Insertion Kits, Introducer Sets (Sheath / Dilators), Catheter Extenders and Arrow Pump Adapters) to Provide Counterpulsation Therapy

Page 2 of 2

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