Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 104155 0005 Rev. 00

Manufacturer:

Datascope Corp
15 Law Drive
Fairfield NJ 07004
USA

Product Category(ies): **Intra-Aortic Balloon Catheters and Kits, Guidewires for Cardiology, Related Accessories: Introducer Sets (Sheath/Dialator), Intra-Aortic Balloon Catheter Extender Tubings, and Arrow Pump Adapter**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 104155 0005 Rev. 00

Report No.: 72157951

Valid from: 2021-04-16
Valid until: 2024-05-26

Date, 2021-04-16

Christoph Dicks
Head of Certification/Notified Body