



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 039555 0198 Rev. 01

Manufacturer:

Edwards Lifesciences LLC

One Edwards Way
Irvine CA 92614
USA

Product Category(ies):

- Hemodynamic Monitoring Equipment
- Hemodynamic Monitoring Disposables
- Medical Devices used for the Diagnosis of Coronary Artery Disease
- Medical Devices used in the Diagnosis and Treatment of Peripheral Vascular Disease
- Medical Devices for the Treatment of Diseases of the Heart and the Central Circulatory System

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:G10395550198Rev.01

Report No.:

72150159

Valid from:

2019-10-29

Valid until:

2024-05-26

Date,

2020-10-08



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