



EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 012974 0609 Rev. 01

Manufacturer

B. Braun Melsungen AG

Carl-Braun-Str. 1
34212 Melsungen
GERMANY

Product Category(ies):

**Accessories for Angiography, Surgery,
Angiography / Atherectomy and Haemodynamic
Monitoring
(class I sterile)
Procedure Kits, Monitoring sets for invasive
physiological pressure measurement
(article 12 systems and procedure packs)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. 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:G2S 012974 0609 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:G2S_012974_0609_Rev.01)

Report No.: 713167870

Valid from: 2020-10-14

Valid until: 2024-05-26

Date, 2020-10-14

Christoph Dicks
Head of Certification/Notified Body