A4 / 07.17





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 074376 0011 Rev. 00

Manufacturer: SABANA Medizinbedarf GmbH

Alwinenstr. 2 65189 Wiesbaden GERMANY

Facility(ies): SABANA Medizinbedarf GmbH

Alwinenstr. 2, 65189 Wiesbaden, GERMANY

Product Category(ies): Sterile, synthetic absorbable surgical sutures.

Sterile, non-absorbable surgical sutures with or

without needle.

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. See also notes overleaf.

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 Valid from:
 2018-12-05

 Valid until:
 2020-11-17

Date. 2018-12-05

Stefan Preiß

1. Punil

