



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

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 074376 0012 Rev. 00

Manufacturer:

SABANA Medizinbedarf GmbH

Alwinenstr. 2
65189 Wiesbaden
GERMANY

Product:

Sutures

**Sterile, non-absorbable surgical suture with
needle or without needle**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

Report no.:

713130592

Valid from:

2019-05-31

Valid until:

2024-05-26

Date,

2019-05-31

Stefan Preiß

Head of Certification/Notified Body

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Facility(ies): SABANA Medizinbedarf GmbH
Alwinenstr. 2, 65189 Wiesbaden, GERMANY

Model(s): **SABApol**
SABAguard
SABANA PTFE

SABApol

Suture diameter: EP 0,2 to 4 (USP 10-0 to USP 1)

Suture length: ≤ 390 cm

Suture with or without needle

Needle Description:

- Tip shape: Taper, Blunt, Reverse Cutting, Cutting, Diamond, Premium Cutting, Taper Cutting, Spatula, Square
- Length: 3 mm to 90 mm
- Curve: 1/4 circle, 3/8 circle, 1/2 circle, 5/8 circle, Compound Curve, Straight, J Shape

Colour: Dyed (blue) / undyed (natural white)

Coating: None coated

Structure diagrams: Monofilament

Suture quantity: 1-50

SABAguard

Suture diameter: EP 0,2 to 7 (USP 10-0 to USP 5)

Suture length: ≤ 390 cm

Suture with or without needle

Needle Description:

- Tip shape: Taper, Blunt, Reverse Cutting, Cutting, Diamond, Premium Cutting, Taper Cutting, Spatula, Square
- Length: 3 mm to 90 mm
- Curve: 1/4 circle, 3/8 circle, 1/2 circle, 5/8 circle, Compound Curve, Straight, J Shape

Colour: Dyed (green) / undyed (natural white)

Coating: Silicone or uncoated

Structure diagrams:

- Braided: EP 0,3 to 7 (USP 9-0 to USP 5)
- Monofilament: EP 0,2 (USP 10-0)

Suture quantity: 1-50

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TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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SABANA PTFE

Suture diameter: EP 0,2 to 5 (USP 10-0 to USP 2)

Suture length: ≤ 390 cm

Suture with or without needle

Needle Discription:

- Tip shape: Taper, Blunt, Reverse Cutting, Cutting, Diamond, Premium Cutting, Taper Cutting, Spatula, Square
- Length: 3 mm to 90 mm
- Curve: 1/4 circle, 3/8 circle, 1/2 circle, 5/8 circle, Compound Curve, Straight, J Shape

Colour: Undyed (natural white)

Coating: None coated

Structure diagrams: Monofilament

Suture quantity: 1-50

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