



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 011858 0064 Rev. 01

Manufacturer:

PAUL HARTMANN AG

Paul-Hartmann-Str. 12

89522 Heidenheim

GERMANY

Product Category(ies): Medical devices for general and special wound treatment, operating theatre products, bandages and tapes, patient care products for use on the ward and in general practice as well as medical devices with a measuring function.

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:G10118580064Rev.01

Report No.: 713197447

Valid from: 2021-02-02

Valid until: 2024-05-26

Date, 2021-02-02

Christoph Dicks
Head of Certification/Notified Body



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Class IIa medical devices

- Wound management products and dressings
- Special wound closure and covering products
- Sets for patient care
- Surgical wound management products
- Surgical gloves latex
- Surgical gloves non-latex
- Customized surgical procedure sets
- Electronic clinical thermometers
- Electronic blood pressure monitors
- Medical instruments
- Products for Negative Pressure Wound Therapy

Class IIb medical devices

- Impregnated tulle dressings and special dressings
- Hydroactive dressings and accessories
- Products for Negative Pressure Wound Therapy
- Customized surgical procedure sets

Class III medical devices

- Wound Dressing impregnated with Silver (Ag)