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Product Service

# 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 011858 0063 Rev. 00**

**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 products with special purposes.**
**(Class I sterile medical devices)**
**Systems and procedure packs according to Article 12 of Directive 93/42/EEC**

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. See also notes overleaf.

**Report No.:** 713156403_2

**Valid from:** 2019-12-09
**Valid until:** 2024-05-26

**Date,** 2019-12-09

Christoph Dicks
Head of Certification/Notified Body


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

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**No. G2S 011858 0063 Rev. 00**

**Facility(ies):**

PAUL HARTMANN AG
Paul-Hartmann-Str. 12, 89522 Heidenheim, GERMANY

**Class I sterile medical devices**

- First aid products
- Wound dressing pads
- Tamponades
- Swabs
- Adhesive dressings
- Bandages
- Sets for patient care
- Accessories / instruments for patient care
- Examination gloves latex
- Theatre clothing
- Theatre draping systems
- Wound management products based on absorbent cotton gauze
- Medical instruments


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