



# 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](http://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



# 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**

## 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)



Product Service

**Product Names to the Attachment of Certificate  
No. G1 011858 0064 Rev. 01, dated 2021-02-02**

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**Medical devices of the HARTMANN GROUP**

Medical devices of PAUL HARTMANN AG

Class II a medical devices

<i>Item No.</i>	<i>Product Groups/Product Names</i>	<i>Classification in accordance with 93/42/EEC</i>	<i>Rule</i>
<b>3.01</b>	<b>Wound management products and dressings</b> e. g. ES gauze swabs Sterilux ES Sterilux gauze swabs Standard gauze swabs Mulpa swabs Sterilux gauze sponges (USP) Lusan gauze swabs Sterilux gauze swabs on a roll Pagasling Pagalong Medicomp Medicomp extra Absorbent cotton gauze	II a	4 (3 <sup>rd</sup> bullet) / 7
<b>3.02</b>	<b>Special wound closure and covering products</b> e. g. Hydrofilm Hydrofilm non-sterile for Kit Packagers Visulin Hydrofilm plus Tiritas MEDICAL (Light bleeding wounds; waterproof, sterile wound dressing) Omnistrip Omnistrip reinforced Dermaplast Omnistrip Dermaplast MEDICAL (Wound closure strips, sterile) Dermaplast hydrocolloid plaster for: minor wounds abrasions Blisters cold sores corns Tiritas hydrocolloid plaster for: minor wounds abrasions Blisters	II a	4 (3 <sup>rd</sup> bullet)



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cold sores  
 corns  
 Cosmos hydrocolloid plaster for:  
 minor wounds  
 abrasions  
 Blisters  
 cold sores  
 corns  
 DermaActive hydrocolloid plaster for:  
 minor wounds  
 abrasions  
 Blisters  
 cold sores  
 corns  
 DermaPlast EFFECT Abrasion  
 Dermoplast Medical Transparent dressing  
 Dermoplast MEDICAL (Light bleeding  
 wounds; waterproof, sterile wound  
 dressing)  
 Dermoplast MEDICAL (Cuts and lacerations)  
 DermaPlast EFFECT To cut blisters & minor  
 wounds  
 DermaPlast EFFECT blister large  
 DermaPlast EFFECT blister heel  
 DermaPlast EFFECT blister small  
 DermaPlast EFFECT corns  
 DermaPlast EFFECT minor wounds  
 DermaPlast EFFECT cold sores  
 Dermoplast burn plaster  
 Tiritas burn plaster  
 Cosmos burn plaster  
 DermaActive burn plaster  
 Dermoplast MEDICAL (Burns)  
 Tiritas MEDICAL (Burns)  
 DermaPlast EFFECT Burns

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Class II a medical devices

<i>Item No.</i>	<i>Product Groups/Product Names</i>	<i>Classification in accordance with 93/42/EEC</i>	<i>Rule</i>
<b>3.03</b>	<b>Sets for patient care</b> e. g. MediSet, Peha, Sterima - Catheterisation sets - Set for anaesthesia	II a	2 / 4 (3 <sup>rd</sup> bullet) 5 (2 <sup>nd</sup> bullet) / 6 / 7



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- Wound treatment sets /  
wound dressing sets
  - Infusion set
  - Injection set
  - Set for central-venous  
catheterisation
  - Suture set
  - Dialysis set
  - Surgical set
  - Birth set
  - Arthrography set
- e.g. Samu-med
- e.g. DermaPlast / DermaActive wound  
treatment kits for the treatment of  
abrasion, burns, cuts and blisters

**3.04 Surgical wound management products**

II a

7

- e. g. Telatrast surgical absorbents non-sterile:  
Telatex, Telasorb, Telasling,  
Telaprep, Telacomp
- e. g. Telatrast-Module-System sterile:  
Telasorb, Telasorb E, Telasling,  
Telaprep, Telacomp, Telacomp E,  
Sterilux X-ray Gauze Sponges (USP),  
Telatrast non woven sponge,  
Telatrast non woven swab
- e. g. Telaset sterile



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Class II a medical devices

<i>Item No.</i>	<i>Product Groups/Product Names</i>	<i>Classification in accordance with 93/42/EEC</i>	<i>Rule</i>
<b>3.05</b>	<b>Surgical gloves Latex</b> e. g. Peha-taft, Peha-taft classic (powder-free), Peha-micron plus powderfree, Peha-taft plus powderfree, Peha-profile plus powderfree, Peha-taft LATEX, Peha basic LATEX, Peha-micron LATEX, Peha-profile LATEX, Peha-taft classic POWDERED, Peha-taft classic POWDERFREE, Peha-underglove LATEX	II a	7
<b>3.06</b>	<b>Surgical gloves non-Latex</b> e. g. Peha-neon plus powderfree, Peha-isoprene plus powderfree Peha-isoprene LATEXFREE, Peha-neon LATEXFREE, Peha-shield LATEXFREE, Peha-underglove LATEXFREE	II a	7
<b>3.07</b>	<b>Customised surgical procedure sets</b> e.g. Foliodrape Sets / Foliodrape CombiSets for indication-related surgical procedures e.g. for general surgery, ophthalmology, gynaecology, obstetrics, cardiosurgery, chest surgery, vascular surgery, ENT, oral and maxillofacial surgery, neurosurgery, orthopaedics, urology	II a	2 / 6 / 7 / 11



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Class II a medical devices

<i>Item No.</i>	<i>Product Groups/Product Names</i>	<i>Classification in accordance with 93/42/EEC</i>	<i>Rule</i>
<b>3.08</b>	<b>Electronic clinical thermometers</b> e. g. Thermoval basic Thermoval Rapid Thermoval rapid flex Thermoval standard Thermoval kids Thermoval kids flex Cosmos thermometers electronic Thermoval duo scan Thermoval baby	II a	10 (3rd bullet)
<b>3.09</b>	<b>Electronic blood pressure monitors</b> e. g. Tensoval mobile Tensoval comfort Tensoval compact Tensoval duo control Tensoval mobil classic Tensoval comfort classic Veroval duo control	II a	10 (3rd bullet)
<b>3.10</b>	<b>Medical instruments</b>  e. g. Peha-instrument - Scissors - Forceps - Needle holder - Wound hook - Sharp spoon - Basic Set  e. g. MediSet, Sterima - Curette - Forceps - Grooved director - Stylet - Scissors	II a	4 (3rd bullet) / 6



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<b>3.11</b>	<b>Products for negative pressure wound therapy</b> e.g. VivanoTec Pro	<b>Ila</b>	<b>11</b>
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**Medical devices of the HARTMANN GROUP**

Medical devices of PAUL HARTMANN AG

Class II b medical devices

<i>Item No.</i>	<i>Product Groups/Product Names</i>	<i>Classification in accordance with 93/42/EEC</i>	<i>Rule</i>
<b>4.01</b>	<b>Impregnated tulle dressings and special dressings</b> e. g. Grassolind neutral, Atrauman, Branolind, Hydrotüll / Hydrotul, Interface, Atrauman Silicone,	<b>II b</b>	<b>4 (2<sup>nd</sup> bullet)</b>
<b>4.02</b>	<b>Hydroactive dressings and accessories</b> e. g. Hydrosorb Hydrosorb comfort Hydrosorb Gel HydroClean HydroClean cavité HydroClean cavity HydroClean active HydroClean active cavité HydroClean plus HydroClean plus cavity HydroClean mini HydroClean advance HydroClean advance mini HydroClean plus mini HydroClean advance cavity Hydrocoll Hydrocoll concave Hydrocoll sacral Hydrocoll thin Sorbalgon Sorbalgon T Zetuvit plus Resposorb Super Zetuvit Plus Silicone RespoSorb Silicone HydroTac	<b>II b</b>	<b>4 (2<sup>nd</sup> bullet)</b>





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HydroTac comfort  
HydroTac concave  
HydroTac sacral  
HydroTac transparent  
HydroTac transparent comfort  
PermaFoam  
PermaFoam sacral  
PermaFoam concave  
PermaFoam cavity  
PermaFoam comfort  
PermaFoam tracheostomy  
Zetuvit Plus Silicone Border /  
RespoSorb Silicone Border  
HydroTac Border Multisite



Product Service

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**Medical devices of the HARTMANN GROUP**

Medical devices of PAUL HARTMANN AG

Class II b medical devices

<i>Item No.</i>	<i>Product Groups/Product Names</i>	<i>Classification in accordance with 93/42/EEC</i>	<i>Rule</i>
<b>4.03</b>	<b>Products for negative pressure wound therapy</b> e.g. VivanoMed - Foam Kit, Foam Round Kit, Foam Thin Kit, - Foam - Silicone Layer - Abdominal Kit	II b	4 (2 <sup>nd</sup> bullet) / 8
<b>4.04</b>	<b>Customised surgical procedure sets</b> e.g. Foliodrape Sets / Foliodrape CombiSets  for indication-related procedures e.g. for general surgery, ophthalmology, gynaecology, obstetrics, cardiosurgery, chest surgery, vascular surgery, ENT, oral and maxillofacial surgery, neurosurgery, orthopaedics, urology	II b	5, 7, 9

**Class III medical devices**

<b>5.01</b>	<b>Impregnated tulle dressings and special dressings</b> Atrauman Ag	III	13
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### History of revisions:

Initial issue, project no. 71315089

Rev. 01-2007, project no. 71318435  
Rev. 07-2007, project no. 71323864  
Rev. 02-2008, project no. 71332843  
Rev. 03-2009, project no. 71349669  
Rev. 10-2009, project no. 71359891  
Rev. 11-2009, project no. 71361438  
Rev. 12-2010, project no. 71365835  
Rev. 13-2010, project no. 71370423  
Rev. 14-2010, project no. 71372243  
Rev. 15-2011, project no. 71386881  
Rev. 16-2011, project no. 71394684  
Rev. 17-2012, project no. 713005130  
Rev. 18-2012, project no. 713005934  
Rev. 19-2013, project no. 713021659  
Rev. 20-2013, project no. 713023609  
Rev. 21-2014, project no. 713043904 and 713043905  
Rev. 22-2015, project no. 713065784  
Rev. 09-2016, project no. 713091055  
Rev. 10-2016, project no. 713093079  
Rev. 11-2016, project no. 713094281  
Rev. 02-2017, project no. 713100768  
Rev. 03-2017, Projekt Nr. 713119437  
Rev. 01-2018, project no. 713143983  
Rev. 01-2019, project no. 713143983 + 713162860  
Rev. 01-2020, project no. 713156403\_1  
Rev. 01-2021, project no. 713197447

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PS-MHS-AP5**