



Product Service

# 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 16 11 11858 057

**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.  
(Class IIa and IIb medical devices; for a complete list of product groups, see attachment)

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.

**Report No.:**

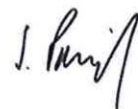
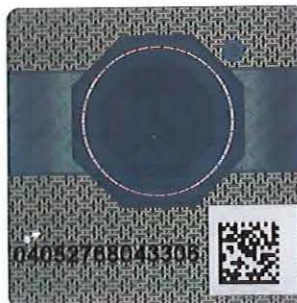
713093079

**Valid from:**

2017-01-21

**Valid until:**

2022-01-20

**Date,** 2016-11-16  
Stefan Preiß

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

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**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 16 11 11858 057****Facility(ies):**

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



Product Service

Attachment for Certificate No. G1 16 11 11858 057  
valid from 2017-01-21

## Medical Devices of the HARTMANN GROUP

Medical Devices of PAUL HARTMANN AG

### Class II a 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
- Customised surgical procedure sets
- Electronic clinical thermometers
- Electronic blood pressure monitors
- Medical instruments
- Products for negative pressure wound therapy

### Class II b medical devices

- Impregnated tulle dressings and special dressings
- Hydroactive dressings and accessories
- Products for negative pressure wound therapy
- Customized surgical procedure sets

Munich, CRT2, 2016-12-20

Stefan Preiß

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**Product Names to the Attachment of Certificate  
No. G1 16 11 11858 057, dated 2017-01-21**

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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 MDD93/42/EEC</i>	<i>Rule</i>
<b>3.01</b>	<b>Wound management products and dressings</b>	<b>II a</b>	<b>7 / 4 (3<sup>rd</sup> bullet)</b>
e. g.	ES gauze swabs, Sterilux ES, Sterilux gauze swabs, Standard gauze swabs, Mulpa swabs, Sterilux gauze sponges (USP), Lusan gauze swabs, Pagasling, Pagalong, Medicomp, Medicomp extra, Absorbent cotton gauze, Sterilux gauze swabs on a roll		
e.g.	Saline solution (0,9%), DermaPlast Clean, Dermaplast MEDICAL (Wound cleansing solution), Lusan Saline Solution		
<b>3.02</b>	<b>Special wound closure and covering products</b>	<b>II a</b>	<b>4 (3<sup>rd</sup> bullet)</b>
e. g.	Hydrofilm, Visulin, Hydrofilm plus, Omnistrip, Omnistrip reinforced, Dermaplast / Tiritas / Cosmos hydro-colloid plaster (e. g. for minor wounds, abrasions, blisters, cold sores and corns), Dermaplast / Tiritas / Cosmos burn plaster, DermaPlast Omnistrip, DermaActive burn plaster, DermaActive hydrocolloid plasters, DermaPlast Medical Transparent dressing, Dermaplast MEDICAL (Light bleeding wounds; waterproof, sterile wound dressing), Dermaplast MEDICAL (Cuts and lacerations), Dermaplast MEDICAL (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 MDD93/42/EEC</i>	<i>Rule</i>
	Tiritas MEDICAL (Burns) DermaPlast EFFECT blister & 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	II a	4 (3 <sup>rd</sup> bullet)
<b>3.03</b>	<b>Sets for patient care</b>	II a	2 / 4 (3 <sup>rd</sup> bullet)
e. g.	MediSet, Peha, Sterima		5 (2 <sup>nd</sup> bullet)
	- Catheterisation sets		/ 6 / 7
	- Set for anaesthesia		
	- 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		



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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>3.04</b>	<b>Surgical wound management products</b>	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 steril		
<b>3.05</b>	<b>Surgical gloves Latex</b>	II a	7
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		
<b>3.06</b>	<b>Surgical gloves non-Latex</b>	II a	7
e. g.	Peha-neon plus powder-free, Peha-isoprene plus powderfree Peha-isoprene LATEXFREE, Peha-neon LATEXFREE, Peha-shield LATEXFREE, Peha-underglove LATEXFREE		



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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>3.07</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, CombiSet	II a	e.g. 2 / 6 / 7 / 11
<b>3.08</b>	<b>Electronic clinical thermometers</b> e. g. Thermoval basic / rapid / rapid flex / duo scan / standard / kids / kids flex, Cosmos thermometers electronic, Thermoval baby	II a	10 (3rd bullet)
<b>3.09</b>	<b>Electronic blood pressure monitors</b> e. g. Tensoval mobil, Tensoval comfort, Tensoval compact, Tensoval duo control, Tensoval mobil classic, Tensoval comfort classic	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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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>3.11</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, Atrauman Ag, Branolind, Hydrotüll / Hydrotul, Syspur-derm, Interface Atrauman Silicone, Dermaplast MEDICAL (Wounds at risk of infection)	II b	4 (2 <sup>nd</sup> bullet)
<b>4.02</b>	<b>Hydroactive dressings and accessories</b> e. g. Hydrosorb, Hydrosorb plus, Hydrosorb comfort, Hydrosorb Gel, AquaClear, AquaClear adhesive, TenderWet, TenderWet 24, Tender- Wet 24 active, TenderWet active cavity, TenderWet Solution, Tender- Wet Duo, TenderWet plus, TenderWet plus cavity HydroClean, HydroClean cavité, HydroClean active, HydroClean active cavité, HydroClean Solution, HydroClean advance, HydroClean mini, HydroClean plus mini, HydroClean advance mini, Hydrocoll, Hydrocoll concave, Hydrocoll sacral, Hydrocoll thin, Sorbagon, Sorbagon T, Sorbagon plus, PermaFoam, PermaFoam sacral, PermaFoam concave, PermaFoam cavity, PermaFoam comfort; PermaFoam tracheostomy, Zetuvit plus, Resposorb Super, Zetuvit Plus Silicone, RespSorb Silicone HydroTac, HydroTac comfort, HydroTac sacral, HydroTac transparent, HydroTac transparent comfort, HydroTac concave HydroClean cavity, HydroClean plus / HydroClean plus cavity	II b	4 (2 <sup>nd</sup> bullet)



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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, CombiSet	II b	e.g. 5, 7, 9



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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, project no. 713119437

**Hamburg, 2017-11-06**

  
**Hendrik Schorler**  
**AMP5 – Department Manager**

