



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 16 11 11858 056**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; for a complete list of product groups, see attachment)****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.:

713093080

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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No. G2S 16 11 11858 056

Facility(ies):

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



Product Service

Attachment for Certificate no G2S 16 11 11858 056
valid from 2017-01-21

Medical devices of the HARTMANN GROUP

Medical devices of PAUL HARTMANN AG

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

Munich, MHS-CRT, 2016-11-16

Stefan Preiß





Product Service

**Product Names to Attachment for Certificate No.
G2S 16 11 11858 056, dated 2017-01-21**

Medical devices of the HARTMANN GROUP

Medical devices of PAUL HARTMANN AG

Class I sterile medical devices

<i>Item No.</i>	<i>Product Groups/Product Names</i>	<i>Classification in accordance with 93/42/EEC</i>	<i>Rule</i>
2.01	First aid products e. g. First aid sheets, Sterilux first aid packet	I sterile	4 (1 st bullet)
2.02	Wound dressing pads e. g. Zetuvit, Zetuvit E, Scrylin, Comprigel, Medicomp Drain, DermaPlast non-woven swabs, DermaPlast Medical swabs, Absoplaie, Samu steril, Peha slit dressings, Non-woven swabs, DermaPlast Medical non-woven swabs	I sterile	4 (1 st bullet)
2.03	Tamponades e. g. Tampograss, tamponing bandages	I sterile	5 (2 nd bullet)
2.04	Swabs e. g. Pur-Zellin, gauze swabs	I sterile	4 (1. bullet)
2.05	Adhesive dressings e. g. Cosmopor steril, Cosmopor E steril, Cosmopor I.V., Sterifix, DermaPlast sensitive sterile, Hydrofilm I.V., Hydrofilm I.V. control, Cosmopor antibacterial, Cosmopor advance, Cosmopor waterproof, Cosmopor skin color, DermaPlast Medical non-woven dressing, Dermaplast MEDICAL (Light bleeding wounds; breathable, sterile wound dressing)	I sterile	4 (1. bullet)
2.06	Bandages e. g. Conforming and compression bandages; padding bandages Rolta, Rolta soft, Sterilux cut gauze bandage roll, Sterilux Bulky Gauze Bandage	I sterile	1, 4 (1. bullet)



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2.07	Sets for patient care	I sterile	1 / 2 / 4 (1 st bullet) / 5 (1 st bullet)
e. g.	MediSet, Peha, Sterima		
	- Dental-Set, mouth care set		
	- Dialysis-Set, set for dent		
	- Wound treatment / dressing set		
	- Injection set		
	- Baby care set		
	- Anaesthesia set		
	- Catheterisation sets		
	- Suture removal set		
	- Maternity set		
	- Pose set for peripheral catheterization		
	- Suture set		
	- Surgical Preparation Kit		
	- Minor surgical set		
	- Set for central-venous catheterization		
2.08	Accessories / instruments for patient care	I sterile	1 / 4 (1 st bullet) / 5 (1 st bullet)
e. g.	MediSet, Peha, Sterima		
	- Applicator		
	- Non-woven balls		
	- Cotton buds		
	- Protective clothing		
	- Tongue depressor		
e. g.	Aqua dest. syringe		
e. g.	Tongue depressor		
e. g.	VivanoTec Port		
e. g.	VivanoTec Y-Connector		
e. g.	Foliodrape Comfort neonatal wrap		
e. g.	Peha-soft nitrile sterile		
e. g.	VivanoTec Exudate Canister		



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2.09	Examination gloves latex e. g. Peha-soft, Peha-soft powderfree	I sterile	5 (1 st bullet)
2.10	Theatre clothing e. g. Foliodress S, Foliodress protect, Foliodress comfort, Foliodress gown protect, Foliodress gown comfort, Foliodress S comfort	I sterile	1
2.11	Theatre draping systems e. g. Foliodrape comfort, Foliodrape protect, Foliodrape protect plus, Foliodrape Accessories	I sterile	1
	e. g. CombiSet		e.g. 1, 4 or 5
2.12	Wound care products based on absorbent cotton gauze e. g. Eycopad, Gauze swabs, Cosmoplast Universal gauze swabs, ES-umbilical pads, Econolux, DermaPlast Faltkompressen, Sterilux cut gauze, Sterilux gauze jacket, Dermaplast MEDICAL (Gauze Swab)	I sterile	1/ 4 (1 st bullet)



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2.13 Medical instruments

I sterile

1 / 4 (1st bullet) /
5 (1st bullet)

- e. g. Peha-instrument
 - Tubing clamp
 - Scissors
- e. g. MediSet, Peha, Sterima
 - Bandage scissors
 - Scissors
 - Forceps / clamp
 - Dental mirror
 - Curette
 - Disposable forceps, tweezers
 - Stitch cutter
 - Needle holder
 - Staple remover
 - Dental explorer

History of revisions:

Initial issue, project no. 71315089
Rev. 07-2007, project no. 71323866
Rev. 03-2009, project no. 71349669
Rev. 04-2009, project no. 71361439
Rev. 05-2010, project no. 71365837
Rev. 06-2011, project no. 71386881
Rev. 07-2011, project no. 71394684
Rev. 08-2012, project no. 713000943
Rev. 09-2012, project no. 713005130
Rev. 10-2013, project no. 713021659
Rev. 11-2014, project no. 713043904
Rev. 12-2015, project no. 713065782
Rev. 09-2016, project no. 713091054
Rev. 10-2016, project no. 713093080
Rev. 02-2017, project no. 713100768
Rev. 03-2017, project no. 713119437

Hamburg, 2017-11-06


Hendrik Schorler
AMP5, Department Manager

