



Product Service

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

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>
3.01	Wound management products and dressings 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 rd bullet) / 7
3.02	Special wound closure and covering products 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 rd 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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3.03	Sets for patient care e. g. MediSet, Peha, Sterima - Catheterisation sets - Set for anaesthesia	II a	2 / 4 (3 rd bullet) 5 (2 nd 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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3.05	Surgical gloves Latex 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
3.06	Surgical gloves non-Latex 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
3.07	Customised surgical procedure sets 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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3.08	Electronic clinical thermometers 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)
3.09	Electronic blood pressure monitors 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)
3.10	Medical instruments 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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3.11	Products for negative pressure wound therapy e.g. VivanoTec Pro	IIa	11
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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>
4.01	Impregnated tulle dressings and special dressings e. g. Grassolind neutral, Atrauman, Branolind, Hydrotüll / Hydrotul, Interface, Atrauman Silicone,	II b	4 (2nd bullet)
4.02	Hydroactive dressings and accessories 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	II b	4 (2nd bullet)



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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



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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>
4.03	Products for negative pressure wound therapy e.g. VivanoMed - Foam Kit, Foam Round Kit, Foam Thin Kit, - Foam - Silicone Layer - Abdominal Kit	II b	4 (2 nd bullet) / 8
4.04	Customised surgical procedure sets 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

5.01	Impregnated tulle dressings and special dressings Atrauman Ag	III	13
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Rev. 01-2007, project no. 71318435
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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
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