

ATTESTATION CE / EC CERTIFICATE

Approbation du Système Complet d'assurance Qualité/ Approval of full Quality Assurance System

ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices

Pour les dispositifs de classe III, un certificat CE de conception est requis

For class III devices, a EC design certificate is required

Fabricant / Manufacturer

PHARMAPLAST SAE

Amria Free Zone, 23512

ALEXANDRIA EGYPT

Catégorie du(des) dispositif(s) / Device(s) category

Pansements stériles et non stériles pour blessures et brûlures

Sterile and Non sterile Wound and Burn Dressings

Voir document complémentaire GMED / See GMED additional document

n° 38016

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé T001292, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced T001292, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4.

La validité du présent certificat est soumise à une vérification périodique ou imprévue

The validity of the certificate is subject to periodic or unexpected verification

Début de validité / Effective date : March 30th, 2021 (included)

Valable jusqu'au / Expiry date : May 26th, 2024 (included)



DocuSigned by:

Beatrice Lys

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On behalf of the President

Béatrice LYS

Technical Director

Ce document complémentaire GMED n° 38016 rev. 1 atteste de la validité du certificat CE n° 27236 rev. 19 au regard des informations listées ci-dessous.

This GMED additional document N° 38016 rev. 1 attests to the validity of CE certificate n° 27236 rev. 19 with regard to the information listed below.

Fabricant / Manufacturer: **Pharmaplast SAE**
Amria Free Zone,
Alexandria, Egypt, 23512

Ce certificat couvre les activités suivantes (description détaillée complète) :

This certificate covers the following activities (full detailed description):

Pansement hydrocolloïde absorbant, pansement hydrogel amorphe stérile et pansement hydrogel amorphe non stérile, pansement silicone de faible adhérence stérile, pansement Lipocolloid de faible adhérence stérile, pansement super-absorbant stérile, pansement stérile de mousse super-absorbante stérile, pansement hydrofibre stérile, pansements d'hydrogels stériles et non stériles, compresses stériles imprégnées non adhésives, lingettes salines stériles, Pansements doublés de mousse hydrogel stérile et pansement à l'alginate stérile

Absorbent Hydrocolloid dressing, sterile amorphous hydrogel wound dressing and non-sterile amorphous hydrogel wound dressing, sterile low adherent silicone wound dressing, sterile low adherent Lipocolloid wound dressing, sterile superabsorbent wound dressing, sterile superabsorbent foam wound dressing, sterile Hydrofiber wound dressing, Sterile and non-sterile hydrogel wound dressings, Sterile non-adherent impregnated gauze dressings, Sterile saline wipes, Sterile hydrogel foam backed wound dressings and Sterile alginate wound dressings

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Technical Director

Identification des dispositifs / Identification of devices

Description du Dispositif Médical <i>Medical Device Description</i>	Référence Commerciale du Dispositif Médical <i>Medical Device Commercial Reference Number</i>	Classe du Dispositif Médical <i>Medical Device Class</i>
Cure-Aid Foot Care Plasters, Cold Sore Patches & Cure-Aid Hydrocolloid Dressings & Acne Patches	Cure-Aid Foot Care plasters sterile Cure-Aid Foot Care plasters non sterile Cure-Aid Cold sore patches sterile Cure-Aid Cold sore patches non sterile Cure-Aid Foot Care plasters with glycerol sterile Cure-Aid Foot Care plasters with glycerol non sterile Cure-Aid Cold sore patches with glycerol sterile Cure-Aid Cold sore patches with glycerol non sterile Cure-Aid Hydrocolloid Dressings sterile Cure-Aid Hydrocolloid Dressings non sterile Cure-Aid Hydrocolloid Dressings with glycerol sterile Cure-Aid Hydrocolloid Dressings with glycerol non sterile Cure-Aid Acne Patches Boots Pharmaceuticals hydrocolloid dressings 5s Boots Pharmaceuticals hydrocolloid plasters 16s Boots Pharmaceuticals blister plasters medium 5s Boots Pharmaceuticals blister plasters small 6s Boots Pharmaceuticals blister plasters mix 5s Boots Pharmaceuticals blister plasters 5s	IIa
Hydrocolloid wound dressings	Pharmacoll Pharmacoll Thin Pharmacoll Extra Thin Pharmacoll Cushion Pharmacoll Comfort Pharmacoll Comfort Plus	IIb
Cavidagel Sterile hydrogel wound filler with Alginate	Cavidagel Sterile hydrogel wound filler with Alginate	IIb
Sterile amorphous hydrogel wound dressing with alginate	Cavidagel Burn Dressings	IIb

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Description du Dispositif Médical <i>Medical Device Description</i>	Référence Commerciale du Dispositif Médical <i>Medical Device Commercial Reference Number</i>	Classe du Dispositif Médical <i>Medical Device Class</i>
Non-sterile amorphous hydrogel wound and burn dressing	Cavidagel Emergency Burn Gel	IIa
Espuma® Non-Adhesive	Espuma® Non-Adhesive Espuma® Sealed Edges Espuma® C Sealed Edges	IIb
Espuma® Adhesive dressings	Espuma® Adhesive Espuma® C Adhesive Espuma® Adhesive Plus Espuma® Basic Espuma® Basic Adhesive Espuma® Basic S Espuma® Basic S Adhesive	IIb
Foam wound dressing with silicone low adherent wound contact layer	ESPUMA® Gentle ESPUMA® Gentle Comfort Espuma Gentle Lite Espuma Gentle Lite Comfort Espuma Gentle C Comfort Espuma Gentle Lite C Comfort Espuma Gentle Xtra Comfort Espuma Gentle Lite Xtra Comfort Espuma Gentle C Xtra Comfort Espuma Gentle Lite C Xtra Comfort Espuma® Gentle Transfer	IIb
Polyester mesh coated with low adherent silicone	Silotull Silotull® One	IIb

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Polyester mesh coated with lipocolloid low adherent, absorbent matrix, laminated on absorbent top sheet	Lipocolloid Non adhesive dressings: <ul style="list-style-type: none"> • Vilowond Lipo • Espuma Lipo Lipocolloid Island Dressings: <ul style="list-style-type: none"> • Espuma Lipo Comfort • Pharmapore Lipo • Pharmapore PU Lipo • Pharmapore PU Lipo Frame style • Pharmapore Ultra Lipo • Pharmapore IV Lipo • Pharmapore PU IV Lipo 	IIb
Adhesive bandage with Lipocolloid wound pad	Lipo-colloid adhesive OTC bandages: <ul style="list-style-type: none"> • Cure-Aid® Lipo • Cure-Aid® Lipo Dressing strip 	IIa
Polyester mesh coated with lipocolloid low adherent, absorbent matrix	Pharmajelly	IIb

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Acrylic fiber superabsorbent wound dressing eXsorb laminated with active carbon nonwoven top sheet eXsorb with acrylic fibers coated with sodium alginate powder	eXsorb eXsorb Carbon eXsorb Algi eXsorb Island Dressings: <ul style="list-style-type: none"> • Pharmapore eXsorb • Pharmapore eXsorb carbon • Pharmapore PU eXsorb • Pharmapore PU eXsorb frame style • Pharmapore IV eXsorb • Pharmapore PU IV eXsorb • Pharmapore Ultra eXsorb eXsorb Carbon Island Dressings: <ul style="list-style-type: none"> • Pharmapore PU eXsorb carbon • Pharmapore PU eXsorb carbon frame style • Pharmapore Ultra eXsorb carbon 	IIb
Adhesive bandage with superabsorbent wound pad eXsorb	eXsorb OTC bandages: <ul style="list-style-type: none"> • Cure-Aid eXsorb • Cure-Aid eXsorb Dressing Strip 	IIa
Pharma-Algi® F non-adherent dressings	Pharma-Algi® F Pharma-Algi® F Carbon	IIb
Pharma-Algi® F Adhesive Island Dressings with or without Carbon	Pharma-Algi® F Adhesive Pharma-Algi® F Carbon Adhesive Pharma-Algi® F Adhesive Film Pharma-Algi® F Carbon Adhesive Film Pharma-Algi® F Adhesive Film Frame style Pharma-Algi® F Carbon Adhesive Film Frame style Pharma-Algi® F Adhesive Ultra Pharma-Algi® F Carbon Adhesive Ultra	IIb

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I.V. Dressing with Pharma-Algi® F Pad	Pharma-Algi® F IV Pharma-Algi® F IV Film Pharma-Algi® F IV Film Frame Style	IIa
Pharma-Algi® F OTC bandages	Pharma-Algi® F Adhesive Bandages Pharma-Algi® F Dressing strip	IIa
Fibrosol non adherent wound pad	Fibrosol non adhesive Fibrosol Extra non adhesive	IIb
Fibrosol Island Dressings	Fibrosol Adhesive Fibrosol Extra Adhesive Fibrosol Adhesive Film Fibrosol Extra Adhesive Film Fibrosol Adhesive Film frame style Fibrosol Extra Adhesive Film frame style Fibrosol Ultra Adhesive Fibrosol Extra Ultra Adhesive	IIb
Fibrosol foam dressings	Fibrosol Foam Gentle Fibrosol Extra Foam Gentle Fibrosol Foam Basic Fibrosol Extra Foam Basic	IIb
Fibrosol IV dressings	Fibrosol IV Fibrosol Extra IV Fibrosol IV film Fibrosol Extra IV film	IIa
Fibrosol OTC bandages	Fibrosol Adhesive bandages Fibrosol Dressing strip	IIa
Sterile and non-sterile hydrogel wound dressings	Pharmagel Pharmagel comfort Absoclear Absoclear comfort	IIb

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Sterile and non-sterile hydrogel wound dressings	Absoclear OTC sterile Absoclear OTC nonsterile	IIa
Sterile non-adherent impregnated gauze dressings	Pharmatull	IIa
Sterile saline wipes	Salicol	IIa
Sterile amorphous hydrogel wound dressings	Kemagel Amorphous	IIb
Sterile hydrogel foam backed wound dressings	All Wound Dressing	IIb
Sterile alginate wound dressings	PharmaAlgi	IIb
	PharmaAlgi Island dressings	
	PharmaAlgi OTC	IIa
Adhesive Hydrogel bandages	Cure-Aid® Hydrogel bandages sterile Cure-Aid® Hydrogel bandages nonsterile	IIa
Hydroactive Colloid paste	Cavicoll	IIb
Silicone based Gel/Sheet/Serum	Cure-Aid Scar Reduction Patch Kemagel® Silicone KemaSerum	IIa
Aluminized wound dressing	AluBurn AluBurn Adhesive AluBurn Adhesive Film AluBurn Adhesive Film Frame Style AluBurn Adhesive Ultra	IIb

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Aluminized wound dressing	AluBurn OTC Bandages AluBurn Conforming Bandages AluBurn I.V. AluBurn I.V. Film AluBurn I.V. Film Frame Style	IIa

Sites couverts et Activités / Locations and Activities

Sites / Locations	Activités / Activities
Pharmaplast S.A.E. Amria Free Zone Alexandria, 23512, Egypt	Conception, Fabrication et contrôle final / Design, Manufacturing and final control
Bulgaria Site KRE LTD, Industrial area Katunsi Sandanski 2830, Bulgaria	Conception, Fabrication et contrôle final / Design, Manufacturing and final control
Borg El Arab Part number 2, block 7, third industrial zone, Borg el Arab, Alexandria, Egypt	Conception, Fabrication et contrôle final / Design, Manufacturing and final control

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