

## 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 détails sur addendum / See attachment for additional information

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé T000171ER, 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 T000171ER, 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 : **April 1st, 2020 (included)**

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



On behalf of the President

**Béatrice LYS**

Technical Director

DocuSigned by:  
Béatrice Lys  
EF338DA9BA04A3...

**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

**Identification des dispositifs / Identification of devices**

<b>Description du Dispositif Médical</b> <i>Medical Device Description</i>	<b>Référence Commerciale du Dispositif Médical</b> <i>Medical Device Commercial Reference Number</i>	<b>Classe du Dispositif Médical</b> <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	IIa

**GMED 0459**



**On behalf of the President**  
**Béatrice LYS**  
**Technical Director**

DocuSigned by:  
*Béatrice Lys*  
EF33BD9A9BA04A3...

<b>Description du Dispositif Médical</b> <i>Medical Device Description</i>	<b>Référence Commerciale du Dispositif Médical</b> <i>Medical Device Commercial Reference Number</i>	<b>Classe du Dispositif Médical</b> <i>Medical Device Class</i>
	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	
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
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	IIb

**GMED 0459**



**On behalf of the President**  
**Béatrice LYS**  
 Technical Director

DocuSigned by:  
*Béatrice Lys*  
 EF33BD49BA0A0A3...

<b>Description du Dispositif Médical</b> <i>Medical Device Description</i>	<b>Référence Commerciale du Dispositif Médical</b> <i>Medical Device Commercial Reference Number</i>	<b>Classe du Dispositif Médical</b> <i>Medical Device Class</i>
	Espuma Gentle Lite Xtra Comfort Espuma Gentle C Xtra Comfort Espuma Gentle Lite C Xtra Comfort Espuma <sup>®</sup> Gentle Transfer	
Polyester mesh coated with low adherent silicone	Silotull Silotull <sup>®</sup> One	IIb
Polyester mesh coated with lipocolloid low adherent, absorbent matrix, laminated on absorbent top sheet	Lipocolloid Non adhesive dressings: <ul style="list-style-type: none"> <li>• Vilowond Lipo</li> <li>• Espuma Lipo</li> </ul> Lipocolloid Island Dressings: <ul style="list-style-type: none"> <li>• Espuma Lipo Comfort</li> <li>• Pharmapore Lipo</li> <li>• Pharmapore PU Lipo</li> <li>• Pharmapore PU Lipo Frame style</li> <li>• Pharmapore Ultra Lipo</li> <li>• Pharmapore IV Lipo</li> <li>• Pharmapore PU IV Lipo</li> </ul>	IIb
Adhesive bandage with Lipocolloid wound pad	Lipo-colloid adhesive OTC bandages: <ul style="list-style-type: none"> <li>• Cure-Aid<sup>®</sup> Lipo</li> <li>• Cure-Aid<sup>®</sup> Lipo Dressing strip</li> </ul>	IIa
Polyester mesh coated with lipocolloid low adherent, absorbent matrix	Pharmajelly	IIb
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"> <li>• Pharmapore eXsorb</li> <li>• Pharmapore eXsorb carbon</li> <li>• Pharmapore PU eXsorb</li> <li>• Pharmapore PU eXsorb frame style</li> <li>• Pharmapore IV eXsorb</li> </ul>	IIb

**GMED 0459**



**On behalf of the President**  
**Béatrice LYS**  
 Technical Director

DocuSigned by:  
*Béatrice Lys*  
EF33BD98BA04A3...

<b>Description du Dispositif Médical</b> <i>Medical Device Description</i>	<b>Référence Commerciale du Dispositif Médical</b> <i>Medical Device Commercial Reference Number</i>	<b>Classe du Dispositif Médical</b> <i>Medical Device Class</i>
	<ul style="list-style-type: none"> <li>Pharmapore PU IV eXsorb</li> <li>Pharmapore Ultra eXsorb</li> </ul> <p>eXsorb Carbon Island Dressings:</p> <ul style="list-style-type: none"> <li>Pharmapore PU eXsorb carbon</li> <li>Pharmapore PU eXsorb carbon frame style</li> <li>Pharmapore Ultra eXsorb carbon</li> </ul>	
Adhesive bandage with superabsorbent wound pad eXsorb	eXsorb OTC bandages: <ul style="list-style-type: none"> <li>Cure-Aid eXsorb</li> <li>Cure-Aid eXsorb Dressing Strip</li> </ul>	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
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 adhesive wound pad	Fibrosol non adhesive Fibrosol Extra non adhesive	IIb

**GMED 0459**



**On behalf of the President**  
**Béatrice LYS**  
**Technical Director**

DocuSigned by:  
*Béatrice Lys*  
EF33BDAB8AA04A3...

<b>Description du Dispositif Médical</b> <i>Medical Device Description</i>	<b>Référence Commerciale du Dispositif Médical</b> <i>Medical Device Commercial Reference Number</i>	<b>Classe du Dispositif Médical</b> <i>Medical Device Class</i>
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
	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

**GMED 0459**



**On behalf of the President**  
**Béatrice LYS**  
 Technical Director

DocuSigned by:  
*Béatrice Lys*  
EF33BD9A9BA04A3...

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>
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

**Ce certificat couvre le site suivant / This certificate covers the following site:**

Pharmaplast S.A.E.  
 Amria Free Zone 23512, Alexandria, Egypt

**Activités effectuées en ce site / Activities performed on this site:**

**Conception, fabrication et contrôle final / Design, manufacturing, and final control**

\*\*\*\*\*

**1 site / 1 site**

**GMED 0459**



**On behalf of the President**  
**Béatrice LYS**  
 Technical Director

DocuSigned by:  
*Béatrice Lys*  
 EF33BD498A04A3...