

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

**Pansement hydrocolloïde absorbant, pansement hydrogel amorphe stérile, pansement
Lipocolloid de faible adhérence stérile et pansement stérile super-absorbant**

*Absorbent Hydrocolloid dressing, sterile amorphous hydrogel wound dressing,
sterile low adherent silicone wound dressing, sterile low adherent Lipocolloid wound dressing, and sterile
superabsorbent wound dressing*

Voir détails sur addendum / See attachment for additional information

Le LNE/G-MED atteste qu'à l'examen des résultats figurant dans le rapport référencé P121496-ADD, 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.

LNE/G-MED certifies that, on the basis of the results contained in the file referenced P121496-ADD, 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 : December 5th, 2014 (included)

Valable jusqu'au / Expiry date : April 6th, 2017 (included)



**For the General Director
Laurence DAGALLIER
Deputy Director**

Identification des dispositifs / Identification of devices

Device Description	Commercial Reference	MD Class
Cure-Aid Foot Care Plasters & Cold Sore 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	Ila
Cavidagel Sterile hydrogel wound filler with Alginate	Cavidagel Sterile hydrogel wound filler with Alginate	Iib
Foam wound dressing with silicone low adherent wound contact layer	ESPUMA® Gentle ESPUMA® Gentle Comfort	Iib
Polyester mesh coated with low adherent silicone	Silotull	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	Iib
Adhesive bandage with superabsorbent wound pad eXsorb	Cure-Aid eXsorb	Ila
Polyester mesh coated with lipocolloid low adherent, absorbent matrix, laminated on absorbent top sheet	Lipocolloid Adhesive and non-adhesive dressings	Iib
Adhesive bandage with Lipocolloid wound pad	Cure-Aid Lipo	Ila

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

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



LNE/G-MED 0459

**For the General Director
Laurence DAGALLIER
Deputy Director**

ADD

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