

ATTESTATION CE / EC CERTIFICATE

Approbation du Système d'assurance Qualité de la Production (limitée à l'obtention et au maintien de l'état stérile)

Approval of Production Quality Assurance System (related to securing and maintaining sterile conditions)

ANNEXE V point 3 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX V section 3 DIRECTIVE 93/42/EEC concerning medical devices

Fabricant / Manufacturer

PHARMAPLAST SAE

Amria Free Zone, 23512

ALEXANDRIA EGYPT

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

Pansements absorbants stériles, non adhésifs stériles, pansements stériles utilisés en premiers soins, champs opératoires stériles, bandes adhésives stériles pour fermetures de plaies et bandes adhésives stériles pour fixation de cathéters

Absorbent, non-adherent sterile dressing, Sterile wound dressings, Sterile First Aid dressings, Sterile theatre incise drapes, Sterile skin closure strips and Sterile catheter securement dressings

Voir document complémentaire GMED / See GMED additional document

n° 38017

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé T001042, le système d'assurance qualité - pour l'obtention et le maintien de l'état stérile - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe V point 3 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced T001042, the quality system - for the quality system for securing and maintaining sterile conditions - of medical devices listed here aboved complies with the requirements of the Directive 93/42/EEC, annex V section 3.

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 : February 17th, 2021 (included)

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



DocuSigned by:

Beatrice lys

EF33BDA9BAA04A3...

On behalf of the President

Béatrice LYS

Technical Director

Ce document complémentaire GMED n° 38017 rev. 1 atteste de la validité du certificat CE n° 27237 rev. 8 au regard des informations listées ci-dessous.

This GMED additional document N° 38017 rev. 1 attests to the validity of CE certificate n° 27237 rev. 8 with regard to the information listed below.

Fabricant / Manufacturer:

**Pharmaplast SAE
Amria Free Zone,
Alexandria, Egypt, 23512**

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>
Absorbent non-adherent Sterile dressing	Vilowond pad Vilowond carbon Vilowond carbon plus Vilowond plus	I(s)
Post-operative dressings with silicone low adherent wound contact layer	Pharmapore Gentle Pharmapore PU Gentle Pharmapore PU Gentle Frame style Pharmapore Ultra Gentle Pharmapore IV Gentle Pharmapore PU IV Gentle Pharmapore PU IV Gentle Frame style Protectfilm Gentle Protectfilm Gentle Frame style	
Adhesive plasters with silicone	Cure-Aid Gentle	

GMED 0459

GMED - 38017 rev. 1



DocuSigned by:

Beatrice Lys

EF33BDA9BAA04A3...

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

<p>Sterile wound dressings</p>	<p>Pharmapore Pharmapore PU Pharmapore IV Pharmapore PU IV Pharmapad Phrampad Carbon Protectfilm FlexAgris™ Catheter Securement Device Pharmapore® Catheter Securement Dressing Pharmapore® PU IV Frame Style with FlexAgris™ Vilowond® Gauze Vilowond® Nonwoven Gauza Plus</p>	<p>I(s)</p>
<p>Sterile first Aid dressings</p>	<p>Cure-Aid</p>	
<p>Sterile theatre incise drapes</p>	<p>Incifilm General Surgery Pharma-Drape Universal Set Super I Universal Set I Universal Set II Laparoscopy Set I Laparoscopy Set II Minor Surgery Set Universal Paediatrics Set Gynecology Surgery : Gynecology Set I Gynecology Set II Gynecology / Cystoscopy Set I Obstetrics surgery : Caesarean Section Set II Caesarean Section Set III Orthopedics Surgery : Shoulder Arthroscopy Set I Arthroscopy Set I Arthroscopy Set II Hip Set I Hip Set II Extremity Set I Extremity Set II Vertical Isolation Set I Hand Set Hand / Foot Set I Spinal Set</p>	<p>I(s)</p>

GMED 0459

GMED - 38017 rev. 1



DocuSigned by:

Beatrice Lys

EF33BDA9BAA04A3...

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

Sterile theatre incise drapes	<p>ENT and Maxillofacial Surgery: ENT Set I</p> <p>Urology Surgery : Urology Set I</p> <p>Cardiothoracic Surgery : Cardiovascular Set I Cardiovascular Surgery : Angiography Set I Angiography Set II Neurosurgery Surgery : Neurosurgery Set I</p> <p>Pharma-Drape Sheets : Pharma-Drape PE film Pharma-Drape Bi-laminate Pharma-Drape Tri-laminate Pharma-Drape Adhesive</p>	I(s)
Sterile skin closure strips	Pharmastrip Pharmastrip fabric	I(s)
Sterile catheter securement dressings	Absoclear cushion rings Absoclear cushion tracheostomy Absoclear IV dressings	I(s)

Sites couverts et Activités / Locations and Activities

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

GMED 0459

GMED - 38017 rev. 1



DocuSigned by:

Beatrice Lys

EF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director