

EC Certificate Full Quality Assurance System: EG03/58704

The management system of

Pharmaplast S.A.E

Amria factory, Amria free zone, Alexandria,
Egypt

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 6 January 2014 until 27 October 2017 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 5 September 2015
Issue 4. Certified since 21 March 2003

Certification is based on reports numbered GB/PC 208715

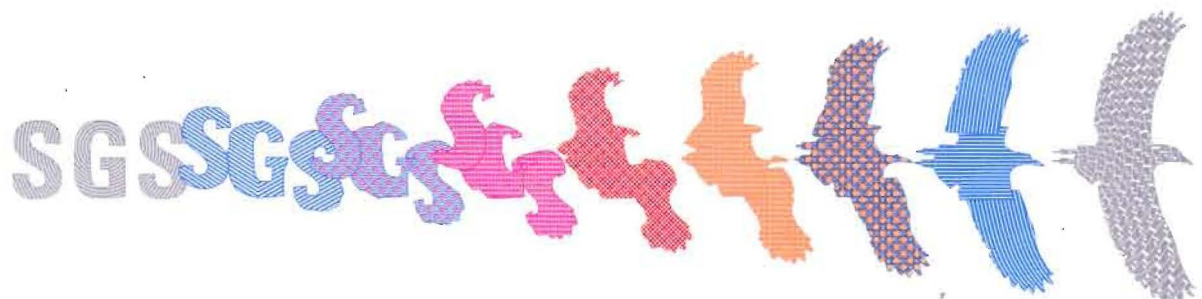
Authorised by

SGS United Kingdom Ltd, Notified Body 0120

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Pharmaplast S.A.E

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 4

Detailed scope

“Domiphen Bromide medicated first aid adhesive wound dressings”.
Sterile “Kemagel” and “Kemagel Comfort” hydrogel dressings. Sterile
“All Wound” dressing. Sterile “Pharmacoll”, Pharmacoll Thin”,
Pharmacoll Basic” and Pharmacoll Comfort” hydrocolloid wound
dressings. Sterile “ESPUMA” and “ESPUMA Comfort” polyurethane
foam wound dressings. Sterile “ESPUMA Silver” and “ESPUMA
Comfort Silver” polyurethane foam with silver wound dressing. Sterile
“Pharmatull” non-adherent paraffin impregnated gauze dressings.
Silver Cure-Aid adhesive plasters and wound dressings. “Pharmapad
Silver”, “Pharmajelly Net” non-adherent lipocolloid impregnated
wound dressing. Sterile “Pharmacoll Ag”, “Pharmacoll Ag Comfort”,
“Pharmacoll Ag Thin”, “Pharmacoll Ag Basic” and “Pharmacoll Ag
OTC” antimicrobial dressings. Hydrocolloid wound dressings
containing silver. Sterile “AbsoClear Gel” and AbsoClear Gel Comfort”
hydrogel dressings, sterile wound dressings, sterile first aid
dressings, sterile Pharmapad carbon wound dressings, Sterile and
non-sterile AbsoClear OTC hydrogel dressings. Sterile ESPUMA
Comfort Plus & ESPUMA Comfort Silver Plus wound dressings. Sterile
“Salicol” saline wipes, sterile Pharma-Algi Alginate wound dressings,
Kemagel® Amorphous sterile healing gel.

For placing on the market of Class III devices covered by this certificate, an EC Design Examination Certificate according to Annex II (Section 4) is required.

Additional facilities

Second Site: Kafr Al-Zayat Factory, P.O. Box 38, Kafr Al-Zayat, Egypt