

SGS

Certificate EG03/58702

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

ISO 13485:2016 EN ISO 13485:2016

For the following activities

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

This certificate is valid from 27 October 2018 until 27 October 2021
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 05 September 2021

Issue 15. Certified since 21 March 2003

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

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Pharmaplast S.A.E.

ISO 13485:2016
EN ISO 13485:2016



Issue 15

Detailed scope

**The design and the manufacture of adhesive tapes,
sterile wound dressings, sterile and non-sterile
First Aid Adhesive wound dressings.
Plaster of Paris bandages, Sterile and non-sterile hydrogel wound
dressings, Sterile hydrogel foam backed wound dressings,
Sterile Polyurethane foam wound dressings,
Sterile non adherent paraffin impregnated gauze dressings,
Sterile Saline wipes, Sterile Alginate wound dressings,
Sterile amorphous hydrogel wound dressings, Sterile Theatre incise
drapes, Sterile Skin Closure Strips & Sterile
Catheter Securement Dressings.**

**The provision of ethylene oxide sterilization for single use medical
devices to the requirements of ISO 11135:2014
as a part of contract manufacturing.**

**The manufacture of Polyolefin, Polyurethane & Co-polyester films,
the manufacture and impregnation of needle-punched nonwoven
fibers, the manufacture of pressure sensitive adhesives
and the manufacture of prepolymers and flexible foam,
for the use in sterile and non-sterile non-active medical devices.**



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Additional facilities

Kafr Al-Zayat Factory, Kafr Al-Zayat, P.O. BOX 38, Egypt