

Certificate EG03/58702.00

The management system of

Pharmaplast S.A.E.

Amria Free Zone, Alexandria, 23512, 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 13 October 2021 until 27 October 2024
and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date.

Issue 22. Certified since 21 March 2003

Multiple certificates have been issued for this scope
The main certificate is numbered EG03/58702.00

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 22



Detailed scope

The design and manufacturing of adhesive tapes, sterile absorbent wound dressings, sterile and non-sterile adhesive absorbent wound dressings, Compression and support bandages, sterile and non-sterile hydrogel wound dressings, sterile and non-sterile hydrocolloid wound dressings, sterile Foam wound dressings, Sterile non-adherent wound contact layers, Sterile saline wipes, Sterile alginate wound dressings, Sterile Theatre incise drapes, Sterile skin closure strips, sterile catheter securement dressings, disposable protective clothing and face masks.

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

The manufacture of extruded polymeric films, manufacture and impregnation of nonwovens, manufacture of pressure sensitive adhesives, manufacture of prepolymers and flexible foams for use in sterile and non-sterile non-active medical devices.

Additional facilities

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

KRE LTD, Industrial area, 2830 Katunsi, Sandanski, Bulgaria

Part number 2, block 7, third industrial zone, Borg el Arab, Alexandria, Egypt



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