



Pharmaplast S.A.E.
Amiria factory
Amria free zone
Alexandria
Egypt

21st November 2012

To Whom it may Concern

This is to confirm that the Quality Management System and Technical Documentation of Pharmaplast S.A.E. located at Amiria factory, Amria free zone, Alexandria, Egypt have been reviewed by SGS United Kingdom Limited and that the following certificates have been issued showing compliance with ISO 13485:2003 and Directive 93/42/EEC Annex II (excluding section 4). These certificates are valid as of the date shown above.

EG03/58702 valid to 27 October 2015 ISO 13485:2003

EG03/58704 valid to 27 October 2017 93/42/EEC Annex II (excluding section 4)

The product scope is shown on the individual certificates and includes the products which have been renamed as follows:

Previous name	New name
<i>Pharma-Foam</i>	<i>Espuma</i>
<i>Pharma-Foam Comfort</i>	<i>Espuma Comfort</i>
<i>Pharma-Foam Silver</i>	<i>Espuma Silver</i>
<i>Pharma-Foam Silver Comfort</i>	<i>Espuma Silver Comfort</i>
<i>Pharma-Foam Comfort Plus</i>	<i>Espuma Comfort Plus</i>
<i>Pharma-Foam Comfort Silver Plus</i>	<i>Espuma Comfort Silver Plus</i>
<i>Pharmagel</i>	<i>Kemagel</i>
<i>Pharmagel Comfort</i>	<i>Kemagel Comfort</i>
<i>PharmaSaline Swab</i>	<i>Salicol</i>

Therefore it can be confirmed that the products shown on certificates EG03/58702 and EG03/58704 have been designed and manufactured within a quality management system that conforms to ISO 13485:2003 and can be placed on the market within the European Union bearing CE 0120 under the responsibility of Pharmaplast S.A.E.

Yours sincerely

David Walden
Medical Devices Technical Coordinator
SGS United Kingdom Limited

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Member of the SGS Group (SA Group)

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