EC Certificate Production Quality Assurance System: Certificate
EG09/79301

The management system of

Kabomed for Medical Industries Company

10th of Ramadan city , B4 piece 174, Egypt

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

For the following products

The scope of registration appears on page 2 of this certificate

This certificate is valid from 10 May 2018 until 22 December 2020 and
remains valid subject to satisfactory surveillance audits.
Re certification audit due before 22 November 2018
Issue 3. Certified since 22 December 2009

Certification is based on reports numbered EG/CAI PI 222860

Authorised by

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SGS CE 13 0311 M2

Kabomed for Medical Industries Company

Directive 93/42/EEC

on medical devices, Annex V

Issue 3

Detailed scope

Annex V
Sterile; Bloodline for haemodialysis, fistula needle for haemodialysis, Blood transfusion set, sterile parenteral bag.

Annex V Sterility aspects only- Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions:
Sterile Drainage bag, Solution infusion set and extension line and sterile enetral bag.

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market.

Additional facilities