EC Certificate Production Quality Assurance System: Certificate PK19/818842631

The management system of

Alshifa Medical Products Co.(CJS)

1st. Industrial City, P.O. Box 7917, Road 22, Cross 11, Dammam 31472
Kingdom of Saudi Arabia

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 04 May 2021 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 6. Certified since 24 April 2014

Certification is based on reports numbered PK/LHR/ 232016

Authorised by

Global Medical Devices Head of Notified Body

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Alshifa Medical Products Co.(CJS)

Directive 93/42/EEC

on medical devices, Annex V

Issue 6

Detailed scope

Sterile, Single-use Hypodermic Syringes with needles.
Sterile, Single-use U-100 Insulin Syringes, Fixed needle, with and without protective end cap.
Sterile, Single-use Auto-Disable Syringes for fixed dose immunization,
Sterile, Single-use Syringes with Re-use Prevention feature (RUP),
Sterile, Single Use Hypodermic Needles
Sterile, Single use Intravenous Cannula
Sterile, Single use Intravenous Cannula with safety feature
Sterile, Single use 3-way Stop Cock
Sterile, Single use 3-way Stop Cock with extension tube
Sterile, Single Use Blood Collection Needle
Sterile, Single Use Insulin Pen Needle
Sterile single use Infusion Set
Sterile Single use Burrete Infusion Set
Sterile single use Needle Free Connector with & without extension tube

Annex V Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions:

Sterile, Single-Use Hypodermic Syringes without needles.

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 the device on the market.