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

Malor

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5008 - Certificate CE1639 AnnexV_EN rev. 02

Page 1 of 2



This document is issued by the Company subject to its General Conditions of Certification Services, unless otherwise agreed, accessible at www.sgs.com/terms_and_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at https://www.sgs.com/en/certified-clients-and-products/certified-client-directory. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.



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 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.