EC Certificate Full Quality Assurance System: Certificate PK20/818842637

The management system of

ABU DHABI MEDICAL DEVICES CO. L.L.C.

Plot 124, M-43, Mussafah, P.O.Box 30485, Abu Dhabi,
United Arab Emirates

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 24 April 2020 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 27 January 2019
and first certified by SGS Belgium NV since 24 April 2020

Certification is based on reports numbered PK/LHR PK19548

Authorised by

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ABU DHABI MEDICAL DEVICES CO. L.L.C.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 1

Detailed scope

MEDECO INJECT Single Use Syringe, Sterile, with needle
MEDECO INJECT Insulin Syringe, Sterile
MEDECO INJECT AD Auto Disable Syringe, Sterile
MEDECO INJECT Hypodermic Needle, Sterile
MEDECO INJECT Reuse Prevention Syringe, Sterile
Auto Disable Needle, Sterile
MEDECO I.V Cannula, Sterile
MEDESET Single Use I.V Infusion Set, Sterile, with needle
MEDECO Burette Set, Sterile, with needle
MEDECO Scalpvein Set, Sterile
MEDECO Yankauer Suction Connection Tube, Sterile
MEDECO Oxygen Mask, Sterile
MEDECO Nebulization Mask, Sterile
MEDECO Nasal Oxygen Cannula, Sterile
MEDECO Endo Tracheal Tube, Sterile
MEDECO Infant Feeding Tube, Sterile
MEDECO Ryles Tube, Sterile
MEDECO Thoracic Catheter, Sterile
MEDECO Blood Transfusion Set, Sterile with needle
MEDECO Suction Catheter, Sterile
MEDECO Nelaton Catheter, Sterile
MEDECO Foley Balloon Catheter, Sterile
MEDECO Three Way Stop Cock, Sterile

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

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