EC Certificate Full Quality Assurance System: Certificate CN19/41099

The management system of

Chengdu OCI Medical Devices Co., Ltd.

No.2401, West Port Avenue, Southwest Airport Economic Development Zone, Shuangliu District, Chengdu, Sichuan Province, 610299, P.R. China

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

Sterile Polyethersulfone Hollow Fiber Hemodialyzer,
Sterile Hemodialysis Blood Tubing Sets,
Sterile Arteriovenous Fistula Needle Sets

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.

This certificate is valid from 16 December 2019 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 02 April 2014
and first certified by SGS Belgium NV since 16 December 2019.

Certification is based on reports numbered CN/SZX 49598

Authorised by

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