

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

**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

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