EC Certificate Full Quality Assurance System: Certificate CN15/20985

The management system of

Suzhou Microclear Medical Instruments Co., Ltd.

A4-409, 410 Biobay, 218 Xinghu Street, Suzhou Industrial Park,
Suzhou City, 215123, Jiangsu Province, 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

Confocal Retina Ophthalmoscope;
Hand-Held Fundus Camera

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 29 July 2018 until 28 July 2023
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 14 January 2021
Issue 4. Certified since 29 July 2015

Certification is based on reports numbered CN/SZH 8611MDD

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0215