

EC Design Examination Certificate: Certificate CN14/10465

Dalian Create Medical Products Co., Ltd.

No. IIB-31, Dalian Export Processing Zone, Dalian, 116600, China

Device Identification:
Sterile Cliny Port System

Intended Purpose of Device:
To be used as an access port (including a catheter) for the long-term infusion of drug solutions

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC on Medical Devices Annex II, section 4

It is certified that the manufacturer's design dossier (and product, where applicable) for the above device has been examined and, based on the evidence submitted, it is considered that the device conforms to the relevant Essential Requirements of EC Directive 93/42/EEC.

This certificate is issued in conjunction with a certificate covering the full quality assurance system to Annex II, which must be subject to satisfactory surveillance audits.

This certificate is valid from 27 January 2019 until 26 April 2019
Issue 4

Certification is based on report number(s) CN/DLC 7783 dated 10 October 2014

Addenda to that report have been issued on the following dates:

Addendum Date
09th April 2018

Reason for Addendum
Change to Tyvek packaging

Authorised by

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