



By Royal Charter

EC Certificate - Full Quality Assurance System

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

No.

CE 588902

Issued To:

Fortune Medical Instrument Corp
6F., No. 29, Sec. 2, Jhongjheng E.Rd.,
Danshuei Dist,
New Taipei City
251
Taiwan

In respect of:

The design, manufacture and final inspection of sterile urological catheters and accessories, drainage tube and accessories, endotracheal tube, tracheostomy tube, reservoir, gastrointestinal tube and accessories, silicone surgical ruler and silicone vessel ID loops and non-sterile laryngeal mask tube.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Albert Roossien, Regulatory Lead

First Issued: 2012-08-27

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

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