

SILICONE FOLEY BALLOON CATHETER

The Right Choice for Quality Catheters



UROLOGICAL
SERIES

SILICONE FOLEY BALLOON CATHETER

Fortune® Silicone 3-Way Foley Catheter Features:

- 100% medical grade silicone for superior biocompatibility.
- Transparent tube with X-ray opaque line.
- A soft and uniformly inflated balloon makes the tube sit well against the bladder.
- 3-Way design with an attached plug on the irrigation funnel.
- Tapered Central funnel could be connected with irrigation bags.
- Includes an individual sterilized packed Catheter Spigot.
- Sterilized double packaging.
- The tip of 3-way Foley Balloon Catheter with open hole, it could be used together with guide wire for difficulty in catheterization.

A Silicone 3-Way Foley Balloon



SPECIFICATIONS

3-Way Foley Balloon Catheter

REF. No.	Size	Balloon	Length	Description
1830-0514	14 FR			
1830-0516	16 FR			
1830-0518	18 FR			
1830-0520	20 FR	20-30 cc/ml	420 mm	Attached plug on flushing port X-ray opaque line Catheter spigot
1830-0522	22 FR			
1830-0524	24 FR			
1830-0526	26 FR			



1830-05XX

EC Certificate - Full Quality Assurance System

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

No.

CE 588902

Issued To:

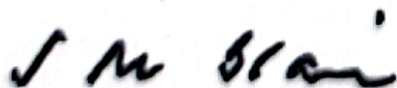
Fortune Medical Instrument Corp
6F., No. 29, Sec. 2, Jhongjheng E.Rd.,
Danshuei Dist,
New Taipei City
251
Taiwan

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 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: 2012-08-27

Date: 2018-10-05

Expiry Date: 2023-09-24

...making excellence a habit.

Page 1 of 1

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.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PR. Tel: +44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7905321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.