



By Royal Charter

EC Certificate - Full Quality Assurance System

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

No.

CE 67878

Issued To:

**Ameco Medical Industries
Industrial Zone B4
Plot 119 East
10th of Ramadan City
Egypt**

In respect of:

Design, development and manufacturing of sterile biopsy needles, Ureteric stent kits, kits and accessories for Urology catheters; dialysis catheters, Central and midline venous catheters, Percutaneous sheath introducers

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: **2002-11-27**

Date: **2017-11-23**

Expiry Date: **2022-11-26**

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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.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.



DECLARATION OF CONFORMITY

- | | |
|---|---|
| 1. Manufacturer name | <u>AMECO MEDICAL INDUSTRIES</u> |
| 2. Manufacturing site | Industrial Zone B4 Plot 119 east,
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| 3. Authorized European Representative: | Obelis s.a
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Fax: +32.2.732.60.03
e-mail : mail@obelis.net
Web: www.obelis.net |
| 4. Device Name: | AMECATH Short Term Haemodialysis Catheters kits

Codes See Annex I from Page 2 to Page 4 |
| 5. Device classification: | Class IIa according to Annex IX Rule 7 MDD 93/42/EEC |
| 6. GMDN: | 40375 |
| 7. Certificate Number: | CE 67878 |
| 8. Notified Body: | BSI (0086)
Kitemark court, Davy Avenue
Knowlhill, Milton Keynes MK5 8PP – United Kingdom
TEL.: +44 (0)845 080 9000 |

We hereby declare that the medical devices specified above meet the Essential requirements listed in Annex 1 of Medical device directive 93/42/EEC and its amendment 2007/47/EC and in compliance with the requirements of Annex II (total quality assurance) excluding Section 4.

Dr. Ibrahim Shalaby
CEO

Ibrahim Shalaby



Annex I

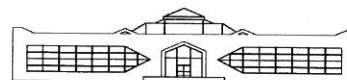
- Codes Key:

Codes	Description
SDLC	Soft Dual Lumen Catheter
K	Standard Subclavian Kit
KJ	Jugular Kit
KJU	Jugular One Side Kit
KPC	Precurved Kit
P	Added to the code for the Pediatric size
N	Added to the code for the Nitinol wire
GS	Added to the code for Guiding Syringe

- Product codes:

1. Single Lumen Catheters

Fr Size	Length	Subclavian Kit Code	Jugular Kit Code	Precurved Kit Code
07	10 Cm	SLC-0710-K	SLC-0710-KJ	SLC-0710-KPC
07	12 Cm	SLC-0712-K	SLC-0712- KJ	SLC-0712- KPC
08	10 Cm	SLC-0810-K	SLC-0810- KJ	SLC-0810- KPC
08	12 Cm	SLC-0812-K	SLC-0812 KJ	SLC-0812- KPC
08	15 Cm	SLC-0815-K	SLC-0815 KJ	SLC-0815- KPC
08	20 Cm	SLC-0820-K	SLC-0820- KJ	SLC-0820- KPC



2. Double lumen catheters:

2.1 Tapered Tip Dual Lumen Catheter Kits

Fr Size	Length	Subclavian Kit Code	Jugular Kit Code	Jugular One Side Kit Code	Precurved Kit Code
06	08 Cm	DLC-0608-KP	XX	XX	XX
07	10 Cm	DLC-0710-KP	DLC-0710-KJP	DLC-0710-KJUP	XX
07	13 Cm	DLC-0713-KP	DLC-0713-KJP	DLC-0713-KJUP	XX
08	10 Cm	DLC-0810-KP	DLC-0810-KJP	DLC-0810-KJUP	XX
08	12 Cm	DLC-0812-KP	DLC-0812-KJP	DLC-0812-KJUP	XX
08	13 Cm	DLC-0813-KP	DLC-0813-KJP	DLC-0813-KJUP	XX
09	10 Cm	DLC-0910-KP	DLC-0910-KJP	DLC-0910-KJUP	XX
09	12 Cm	DLC-0912-KP	DLC-0912-KJP	DLC-0912-KJUP	XX
09	13 Cm	DLC-0913-KP	DLC-0913-KJP	DLC-0913-KJUP	XX
09	13 Cm	DLC-0913-K	DLC-0913-KJ	DLC-0913-KJU	DLC-0913-KPC
09	15 Cm	DLC-0915-K	DLC-0915-KJ	DLC-0915-KJU	DLC-0915-KPC
10	10 Cm	DLC-1010-K	DLC-1010-KJ	DLC-1010-KJU	XX
10	13 Cm	DLC-1013-K	DLC-1013-KJ	DLC-1013-KJU	DLC-1013-KPC
10	15 Cm	DLC-1015-K	DLC-1015-KJ	DLC-1015-KJU	DLC-1015-KPC
12	12 Cm	DLC-1212-K	DLC-1212-KJ	DLC-1212-KJU	DLC-1212-KPC
12	13 Cm	DLC-1213-K	DLC-1213-KJ	DLC-1213-KJU	DLC-1213-KPC
12	15 Cm	DLC-1215-K	DLC-1215-KJ	DLC-1215-KJU	DLC-1215-KPC
12	16 Cm	DLC-1216-K	DLC-1216-KJ	DLC-1216-KJU	DLC-1216-KPC
12	17 Cm	DLC-1217-K	DLC-1217-KJ	DLC-1217-KJU	DLC-1217-KPC
12	20 Cm	DLC-1220-K	DLC-1220-KJ	DLC-1220-KJU	DLC-1220-KPC
12	24 Cm	DLC-1224-K	DLC-1224-KJ	DLC-1224-KJU	DLC-1224-KPC
14	15 Cm	DLC-1415-K	DLC-1415-KJ	DLC-1415-KJU	DLC-1415-KPC
14	17 Cm	DLC-1417-K	DLC-1417-KJ	DLC-1417-KJU	DLC-1417-KPC
14	20 Cm	DLC-1420-K	DLC-1420-KJ	DLC-1420-KJU	DLC-1420-KPC
16	15 Cm	DLC-1615-K	DLC-1615-KJ	DLC-1615-KJU	XX
16	17 Cm	DLC-1617-K	DLC-1617-KJ	DLC-1617-KJU	XX
16	20 Cm	DLC-1620-K	DLC-1620-KJ	DLC-1620-KJU	XX

2.2 Step Tip Soft Dual Lumen Catheter Kits

Fr Size	Length	Subclavian Kit Code	Jugular Kit Code	Jugular One Side Kit Code
12	12 Cm	SDLC-1212-K	SDLC-1212-KJ	XX
12	15 Cm	SDLC-1215-K	SDLC-1215-KJ	SDLC-1215-KJU
12	17 Cm	SDLC-1217-K	SDLC-1217-KJ	SDLC-1217-KJU
12	20 Cm	SDLC-1220-K	SDLC-1220-KJ	SDLC-1220-KJU
12	25 Cm	SDLC-1225-K	SDLC-1225-KJ	SDLC-1225-KJU
14	15 Cm	SDLC-1415-K	SDLC-1415-KJ	SDLC-1415-KJU
14	17 Cm	SDLC-1417-K	SDLC-1417-KJ	SDLC-1417-KJU
14	20 Cm	SDLC-1420-K	SDLC-1420-KJ	SDLC-1420-KJU
14	25 Cm	SDLC-1425-K	SDLC-1425-KJ	SDLC-1425-KJU
14	30 Cm	SDLC-1430-K	SDLC-1430-KJ	SDLC-1430-KJU



14	35 Cm	SDLC-1435-K	SDLC-1435-KJ	SDLC-1435-KJU
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2.3 Uniqath

Fr. Size	Length	Kit Code
12	15 Cm	UN-DLC-1215-K
12	17 Cm	UN-DLC-1217-K
12	20 Cm	UN-DLC-1220-K
12	25 Cm	UN-DLC-1225-K
14	15 Cm	UN-DLC-1415-K
14	17 Cm	UN-DLC-1417-K
14	20 Cm	UN-DLC-1420-K
14	25 Cm	UN-DLC-1425-K

3. Triple lumen catheter

Fr Size	Length	Subclavian Kit Code	Jugular Kit Code	Jugular One Side Kit Code	Precurved Kit Code
12	15 Cm	TLC-1215-K	TLC-1215-KJ	TLC-1215-KJU	TLC-1215-KPC
12	17 Cm	XX	XX	TLC-1217-KJU	XX
12	20 Cm	XX	XX	TLC-1220-KJU	XX
13	15 Cm	TLC-1315-K	TLC-1315-KJ	TLC-1315-KJU	TLC-1315-KPC
13	17 Cm	TLC-1317-K	TLC-1317-KJ	TLC-1317-KJU	TLC-1317-KPC
13	20 Cm	TLC-1320-K	TLC-1320-KJ	TLC-1320-KJU	TLC-1320-KPC
13	24 Cm	TLC-1324-K	TLC-1324-KJ	TLC-1324-KJU	TLC-1324-KPC
13	25 Cm	TLC-1325-K	TLC-1325-KJ	TLC-1325-KJU	TLC-1325-KPC
14	15 Cm	TLC-1415-K	TLC-1415-KJ	TLC-1415-KJU	TLC-1415-KPC
14	17 Cm	TLC-1417-K	TLC-1417-KJ	TLC-1417-KJU	TLC-1417-KPC
14	20 Cm	TLC-1420-K	TLC-1420-KJ	TLC-1420-KJU	TLC-1420-KPC

4. Smart Short Term Dual Lumen Catheter Kit

Fr Size	Length	Subclavian Kit Code	Jugular Kit Code	Precurved Kit Code
12	12 Cm	DLC-1212-KSM	DLC-1212-KJSM	DLC-1212-KPCSM
12	15 Cm	DLC-1215-KSM	DLC-1215-KJSM	DLC-1215-KPCSM
12	17 Cm	DLC-1217-KSM	DLC-1217-KJSM	DLC-1217-KPCSM
12	20 Cm	DLC-1220-KSM	DLC-1220-KJSM	DLC-1220-KPCSM
14	15 Cm	DLC-1415-KSM	DLC-1415-KJSM	DLC-1415-KPCSM
14	17 Cm	DLC-1417-KSM	DLC-1417-KJSM	DLC-1417-KPCSM
14	20 Cm	DLC-1420-KSM	DLC-1420-KJSM	DLC-1420-KPCSM