Certificate

Full Quality Assurance

No. CE 67878

Issued to:

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

In respect of:
The design, development and manufacture of sterile Dialysis catheters, kits and accessories, urology catheters, kits and accessories, central venous catheters, kits and accessories and Percutaneous Sheath Introducer kits

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 3.2.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Gary Fenton, Global Assurance Director

First Issued: **27 Nov 2002** Date: **13 Nov 2012**

Expiration Date: **26 Nov 2017**

Conditions of Approval
Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. 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.

raising standards worldwide™

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: +44 (0)845 080 9000

Certificate

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No.	**CE 67878**
Date:	**13 Nov 2012**
Issued to:	**Ameco Medical Industries**
	10th of Ramadan City
	Egypt

Subcontractor	Service(s) supplied
PRUMENET Route du Pont Coloré F 13 550 Paluds de Noves France	EU Representative

AMECO MEDICAL INDUSTRIES

DECLARATON OF CONFORMITY

1. Manufacturing Address: **AMECO MEDICAL INDUSTRIES**

Administration Office & Manufacturing site:
INDUSTRIAL ZONE B4
BLOT # 119 EAST
10TH OF RAMADAN CITY- EGYPT
TEL: +20.15.383 066/67 FAX: +20.15.383 068
EMAIL: info@amecath.com
WEB: www.amecath.com

2. Authorized European Representative:
PRUMENET
Route du Pont Coloré
F 13 550 PALUDS de NOVES France
Tel: ++ 33 4 90 95 42 53
Fax: ++ 33 4 90 95 02 91

3. Device name: **Single use sterile Haemodialysis Catheters and kits**

4. Class **IIa**

5- Trade Name: **AMECATH**

6- Certificate number ***CE67878***

7- Notified body:
BSI (0086)
MAYLANDS AVENUE -HEMEL HEMPSTEAD
HERTS HP2 4SQ – ENGLAND
TEL.: +44 (0)8450 765600 FAX: +44 (0)8450 765609

7. Product codes:

1- Single lumen kits:

Fr Size	Length	SUBCLAVIAN KIT CODE	JUGULAR KIT CODE	PRECURVED KIT CODE
07	10 Cm	SLC-0710-K	SLC-0710-JK	SLC-0710-PCK
07	12 Cm	SLC-0712-K	SLC-0712-JK	SLC-0712-PCK
08	10 Cm	SLC-0810-K	SLC-0810-JK	SLC-0810-PCK
08	12 Cm	SLC-0812-K	SLC-0812-JK	SLC-0812-PCK
08	15 Cm	SLC-0815-K	SLC-0815-JK	SLC-0815-PCK
08	20 Cm	SLC-0820-K	SLC-0820-JK	SLC-0820-PCK
08	24 Cm	SLC-0824-K	SLC-0824-JK	SLC-0824-PCK

2 – Dual lumen kits:

Fr Size	Length	SUBCLAVIAN KIT CODE	JUGULAR KIT CODE	PRECURVED KIT CODE
06	08 Cm	DLC-0608-KP		
07	10 Cm	DLC-0710-KP	DLC-0710-JKP	
07	13 Cm	DLC-0713-KP	DLC-0713-JKP	
08	10 Cm	DLC-0810-KP	DLC-0810-JKP	
08	13 Cm	DLC-0813-KP	DLC-0813-JKP	
09	10 Cm	DLC-0910-KP	DLC-0910-JKP	
09	13 Cm	DLC-0913-KP	DLC-0913-JKP	
09	15 Cm	DLC-0915-K	DLC-0915-JK	DLC-0915-PCK
10	10 Cm	DLC-1010-KP	DLC-1010-JKP	
10	12 Cm	DLC-1012-K	DLC-1012-JK	DLC-1012-PCK
10	15 Cm	DLC-1015-K	DLC-1015-JK	DLC-1015-PCK
11	12 Cm	DLC-1112-K	DLC-1112-JK	DLC-1112-PCK
11	15 Cm	DLC-1115-K	DLC-1115-JK	DLC-1115-PCK
11	17 Cm	DLC-1117-K	DLC-1117-JK	DLC-1117-PCK
11	20 Cm	DLC-1120-K	DLC-1120-JK	DLC-1120-PCK
11	24 Cm	DLC-1124-K		
12	12 Cm	DLC-1212-K	DLC-1212-JK	DLC-1212-PCK
12	15 Cm	DLC-1215-K	DLC-1215-JK	DLC-1215-PCK
12	17 Cm	DLC-1217-K	DLC-1217-JK	DLC-1217-PCK
12	20 Cm	DLC-1220-K	DLC-1220-JK	DLC-1220-PCK
12	24 Cm	DLC-1224-K		
12	26 Cm	UN-DLC-12-K		
14	15 Cm	DLC-1415-K	DLC-1415-JK	DLC-1415-PCK
14	17 Cm	DLC-1417-K	DLC-1417-JK	DLC-1417-PCK
14	20 Cm	DLC-1420-K	DLC-1420-JK	DLC-1420-PCK
14	26 Cm	UN-DLC-14-K		

3- Step tip soft dual lumen catheter

Fr Size	Length	SUBCLAVIAN KIT CODE	JUGULAR KIT CODE	SIDE JUGULAR KIT CODE
12	15	SDLC-1215-K	SDLC-1215-KJ	SDLC-1215-KJU
12	17	SDLC-1217-K	SDLC-1217-KJ	SDLC-1217-KJU
12	20	SDLC-1220-K	SDLC-1220-KJ	SDLC-1220-KJU
14	15	SDLC-1415-K	SDLC-1415-KJ	SDLC-1415-KJU
14	17	SDLC-1417-K	SDLC-1417-KJ	SDLC-1417-KJU
14	20	SDLC-1420-K	SDLC-1420-KJ	SDLC-1420-KJU
14	30	SDLC-1430-K	SDLC-1430-KJ	SDLC-1430-KJU
14	35	SDLC-1435-K	SDLC-1435-KJ	SDLC-1435-KJU

4- Triple lumen kits:

Fr Size	Length	SUBCLAVIAN KIT CODE	JUGULAR KIT CODE	PRECURVED KIT CODE
13	15 Cm	TLC-1315-K	TLC-1315-JK	TLC-1315-PCK
13	17 Cm	TLC-1317-K	TLC-1317-JK	TLC-1317-PCK
13	20 Cm	TLC-1320-K	TLC-1320-JK	TLC-1320-PCK
13	24 Cm	TLC-1324-K	TLC-1324-JK	TLC-1324-PCK
14	15 Cm	TLC-1415-K	TLC-1415-JK	TLC-1415-PCK
14	17 Cm	TLC-1417-K	TLC-1417-JK	TLC-1417-PCK
14	20 Cm	TLC-1420-K	TLC-1420-JK	TLC-1420-PCK
14	24 Cm	TLC-1424-K	TLC-1424-JK	TLC-1424-PCK

We, the undersigned, 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 are in compliance with the requirements of Annex II section 3.2 (total quality assurance).

Written and approved by	Position	Signature	Date
Dr. Samy Hamboly	CEO		18/07/2013

AMECO MEDICAL INDUSTRIES

1.2

DECLARATION OF CONFORMITY

1. Manufacturing Address: **Administration Office & Manufacturing site:**	**AMECO MEDICAL INDUSTRIES** INDUSTRIAL ZONE B4 BLOT # 119 EAST 10TH OF RAMADAN CITY- EGYPT TEL: +20.15.383 066/67 FAX: +20.15.383 068 EMAIL: info@amecath.com WEB: www.amecath.com
2. Authorized European Representative:	PRUMENET Route du Pont Coloré F 13 550 PALUDS de NOVES France Tel: ++ 33 4 90 95 42 53 Fax: ++ 33 4 90 95 02 91
3. Device name:	Single use sterile long term Central Venous Haemodialysis Catheters and kits
4- Trade Name:	AMECATH
5- Product classification:	Class III
6- Notified body	BSI (0086) MAYLANDS AVENUE -HEMEL HEMPSTEAD HERTS HP2 4SQ – ENGLAND TEL.: +44 (0)8450 765600 FAX: +44 (0)8450 765609

Cath. Code	Description	Kit Code
P1TC	Permthane Single Tube Catheter	PITC-K(A/V/AV)
PDLC	Permthane Dual lumen Catheter	PDLC-K
PDLC-PC	Permthane Pre-curved Dual lumen Catheter	PDLC-KPC
P2TC	Permthane twin tube Catheter	P2TC-K
P2TC -PC	Permthane Pre-curved Twin tube Catheter	P2TC-KPC
PXDLC	Permthane X Split catheter	PXDLC-K
PXDLC-PC	Permthane Pre-curved X Split catheter	PXDLC-KPC
PYDLC	Permthane Y Split catheter	PYDLC-K
PYDLC-PC	Permthane Pre-curved Y Split catheter	PYDLC-KPC

We, the undersigned, 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 including point 4.

Written and approved by	Position	Signature	Issuing and effective Date
Dr. M. SAMY HAMBOLY	CHAIRMAN		01/5/2010