

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

Page: 1 of 1

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*TM



Certificate

List of Significant Subcontractors

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

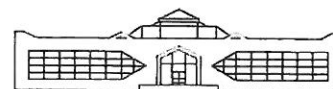
Certificate No. **CE 67878**
Date: **13 Nov 2012**
Issued to: **Ameco Medical Industries**
10th of Ramadan City
Egypt

Subcontractor

Service(s) supplied

PRUMENET
Route du Pont Coloré
F 13 550 Paluds de Noves
France

EU Representative



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**

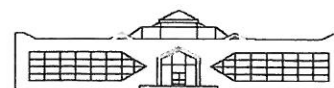
6- Certificate number **CE67878**

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 I 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

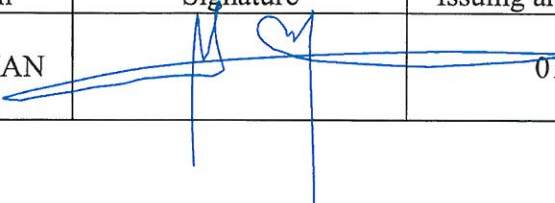


1.2

DECLARATION OF CONFORMITY

1. Manufacturing Address:	<u>AMECO MEDICAL INDUSTRIES</u>																																
Administration Office & Manufacturing site:	INDUSTRIAL ZONE B4 BLOT # 119 EAST 10 TH OF RAMADAN CITY- EGYPT TEL: +20.15.383 066/67 FAX: +20.15.383 068 EMAIL: info@amecath.com WEB: www.amecath.com																																
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3. Device name:	Single use sterile long term Central Venous Haemodialysis Catheters and kits <table border="0"> <thead> <tr> <th>Cath. Code</th> <th>Description</th> <th>Kit Code</th> </tr> </thead> <tbody> <tr> <td>P1TC</td> <td>Permthane Single Tube Catheter</td> <td>P1TC-K(A/V/AV)</td> </tr> <tr> <td>PDLC</td> <td>Permthane Dual lumen Catheter</td> <td>PDLC-K</td> </tr> <tr> <td>PDLC-PC</td> <td>Permthane Pre-curved Dual lumen Catheter</td> <td>PDLC-KPC</td> </tr> <tr> <td>P2TC</td> <td>Permthane twin tube Catheter</td> <td>P2TC-K</td> </tr> <tr> <td>P2TC -PC</td> <td>Permthane Pre-curved Twin tube Catheter</td> <td>P2TC-KPC</td> </tr> <tr> <td>PXDLC</td> <td>Permthane X Split catheter</td> <td>PXDLC-K</td> </tr> <tr> <td>PXDLC-PC</td> <td>Permthane Pre-curved X Split catheter</td> <td>PXDLC-KPC</td> </tr> <tr> <td>PYDLC</td> <td>Permthane Y Split catheter</td> <td>PYDLC-K</td> </tr> <tr> <td>PYDLC-PC</td> <td>Permthane Pre-curved Y Split catheter</td> <td>PYDLC-KPC</td> </tr> </tbody> </table>			Cath. Code	Description	Kit Code	P1TC	Permthane Single Tube Catheter	P1TC-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
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We, the undersigned, hereby declare that the medical devices specified above meet the Essential requirements listed in Annex I 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