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By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 540595**

Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

In respect of:

The design and manufacture of non active digestive tract devices; non active gynecological devices; non active regional anaesthesia devices; non active respiratory devices; non active surgical devices; non active urology devices.

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):

Frank Lee, EMEA Compliance & Risk Director

SOCIETATEA CU RĂSPUNDERE LIMITATĂ «LIFE MED» S.R.L. IDNO 1014600035666 REPUBLICA MOLDOVA, mun. CHIȘINĂU

First Issued: **13 January 2009** Date: **28 August 2015** Expiry Date: **07 September 2020**

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By Royal Charter

EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

Certificate No:	**CE 540595**
Date:	**28 August 2015**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
Arrow International CR, a.s. Jamska 2359/47 59101 Zdar nad Sazavou Czech Republic	**Control of Sterilization** **Design** **Manufacture**
Arrow International CR, a.s. Prazska 209 50004 Hradec Kralove Czech Republic	**Control of Sterilization** **Design** **Manufacture**
Arrow Medical Ltd Hatton Gardens Industrial Estate Kington HR5 3RB United Kingdom	**Crucial Supplier**
CeMed GmbH Oberdorf 41 72419 Neufra Germany	**Control of Sterilization** **Manufacture**

SOCIETATEA CU RĂSPUNDERE LIMITATĂ «LIFE MED» S.R.L. IDNO 1014600035866 REPUBLICA MOLDOVA

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By Royal Charter

EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

Certificate No:	**CE 540595**
Date:	**28 August 2015**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
Chelle Medical Limited PO Box 221 Le Rocher Victoria Mahe Seychelles	**Crucial Supplier**
Forefront (Xiamen) Medical Devices Co., Ltd No 26 & 28 Haijing Dong Lu Haicang Xiamen Export Processing Zone 361026, Xiamen, Fujian China	**Crucial Supplier**
Forefront Medical Technology Pte Ltd 35 Joo Koon Circle, 6th Floor Singapore 629110 Singapore	**Crucial Supplier**

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By Royal Charter

EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

Certificate No:	**CE 540595**
Date:	**28 August 2015**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
M.E.M., Inc. 8 Bishop Lane Madison Connecticut 06443 USA	**Crucial Supplier**
Parker Medical Systems Division - Merrillville 1201 East 86th Place Merrillville Indiana 46410 USA	**Crucial Supplier**
Plaxtron Industrial (M) Sdn. Bhd. Plot 28, Kawasan Perusahaan Jelapang II Zon Perdagangan Bebas 30020 Ipoh Perak Malaysia	**Crucial Supplier**

SOCIETATEA CU RASPUNDERE LIMITATA «LIFE MED» S.R.L. IDNO 1014600035666 REPUBLICA MOLDOVA, mun. CHISINAU

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By Royal Charter

EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

Certificate No: **CE 540595**

Date: **28 August 2015**

Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Subcontractor:	Service(s) supplied
SP Medical A/S Møllevej 1 4653 Karise Denmark	**Control of Sterilization** **Design** **Manufacture**
Süddeutsche Feinmechanik GmbH (SFM) Brückenstrasse 5 D-63607 Wächtersbach Germany	**Control of Sterilization** **Manufacture**
Teleflex Medical Sdn. Bhd. Lot PT2577, Jalan Perusahaan 4 34600 Kamunting Perak Malaysia	**Control of Sterilization** **Design** **Manufacture**
Teleflex Medical Asia Pte. Ltd. 6 Battery Road #07-02 049909 Singapore	**Control of Sterilization** **Design** **Manufacture**

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CERTIFICATE OF FULL QUALITY ASSURANCE

MERIL LIFE SCIENCES PVT. LTD.

located at the adress

MUKTANAND MARG, CHALA, VAPI 396191 GUJARAT, INDIA

for the scope of;

PACLITAXEL ELUTING PTA BALLOON CATHETER
(Mozec™ PEB PTA)

has been examined and certified to the requirements of

93/42/EEC – Medical Device Directive Full Quality Assurance Module – Module H (Annex-II Article 4 Excluded)

by considering the related clauses of TS EN ISO 13485:2012

Notified Body Number:	1783
Certificate Issue Date:	06.06.2018
Valid Until:	06.06.2023
GMDN Code:	62551
EC Design Examination Certificate Number:	1783-MDD-092
Examination Report Number:	1207-MDD-069/2017-01
Date / Reason of the Certificate Revision	-

This certificate remarks that quality system meets requirements of the technical regulations / harmonized standards and with this certificate the company is authorized to affix CE Mark, as shown below, and Notified Body Number on the products in the scope of the examined quality system. Notified Body has the right to carry out surveillance visits announced or unannounced in accordance with section 5 of Annex 2 of Medical Device Directive.
For CE marking the class III devices covered by this certificate, an EC design-examination certificate according to MDD Annex II (4) is also required.

CE

Certificate Number: 1783-MDD-091

SOCIETATEA CU RĂSPUNDERE LIMITATĂ «LIFE MED» S.R.L. IDNO 1014600035666 REPUBLICA MOLDOVA, mun. CHIŞINĂU

TÜRK STANDARTLARI ENSTİTÜSÜ * TURKISH STANDARDS INSTITUTION * DIREKTİFLER MODÜLÜ DIRECTIVE 1783

ZEYNEP FÜSUN DENLİ TUDAN
Deputy Director of Directives
ANKARA Rev 00. 06/06/2018

EC Certificate
Full Quality Assurance System

A DNV GL & NEMKO COMPANY

Certificate No.: **11031-2017-CE-IND-NA-PS Rev. 0.0**

Project No.: **PRJC-57298-2008-PRC-IND**

Valid Until: **30 May 2018**

This is to certify that the quality system of:

Meril Life Sciences Private Limited
Muktanand Marg, Chala, Vapi,
Gujarat,
India-396191

For design, production and final product inspection/testing of:

PTA Balloon Dilatation Catheter

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H2) of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 2nd October 2017

«LIFE MED» S.R.L. IDNO 1014600035666

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Villy Rønneberg

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

EC Certificate
Full Quality Assurance System

A DNV GL & NEMKO COMPANY

Certificate No.: **11031-2017-CE-IND-NA-PS Rev. 0.0**

Project No.: **PRJC-57298-2008-PRC-IND**

Valid Until: **30 May 2018**

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Supersedes DNVGL (NB 0434) Certificate no: 5050-2014-CE-IND-NA Rev 2.0 following transfer to notified body functions to DNV GL Nemko Presafe AS (NB 2460)	2017-10-02

Products covered by this Certificate:

Product Description	Product Name	Class
Mozec™ PTA 0.035" OTW Balloon Dilatation Catheter	• Mozec™ PTA OTW Balloon Dilatation Catheter (OTW 0.035") –sterile & non sterile	IIa

Catalogue Numbers							
Diameter (mm)	Length (mm)						
	20	30	40	50	60	80	120
3.00	MO35030020A	MO35030030A	MO35030040A	MO35030050A	MO35030060A	MO35030080A	MO35030120A
4.00	MO35040020A	MO35040030A	MO35040040A	MO35040050A	MO35040060A	MO35040080A	MO35040120A
5.00	MO35050020A	MO35050030A	MO35050040A	MO35050050A	MO35050060A	MO35050080A	MO35050120A
6.00	MO35060020A	MO35060030A	MO35060040A	MO35060050A	MO35060060A	MO35060080A	MO35060120A
7.00	MO35070020A	MO35070030A	MO35070040A	MO35070050A	MO35070060A	MO35070080A	MO35070120A
8.00	MO35080020A	MO35080030A	MO35080040A	MO35080050A	MO35080060A	MO35080080A	MO35080120A
9.00	MO35090020A	MO35090030A	MO35080040A	MO35090050A	MO35090060A	MO35090080A	
10.00	MO35100020A	MO35100030A	MO35100040A	MO35100050A	MO35100060A	MO35100080A	

For: Catheter with Usable length 800mm

Catalogue Numbers							
Diameter (mm)	Length (mm)						
	20	30	40	50	60	80	120
3.00	MO35030020B	MO35030030B	MO35030040B	MO35030050B	MO35030060B	MO35030080B	MO35030120B
4.00	MO35040020B	MO35040030B	MO35040040B	MO35040050B	MO35040060B	MO35040080B	MO35040120B
5.00	MO35050020B	MO35050030B	MO35050040B	MO35050050B	MO35050060B	MO35050080B	MO35050120B

«LIFE MED» S.R.L. MOLDOVA, mun. CHIȘINĂU

EC Certificate
Full Quality Assurance System

Certificate No.: **11031-2017-CE-IND-NA-PS Rev. 0.0**
Project No.: **PRJC-57298-2008-PRC-IND**
Valid Until: **30 May 2018**

6.00	MO35060020B	MO35060030B	MO35060040B	MO35060050B	MO35060060B	MO35060080B	MO35060120B
7.00	MO35070020B	MO35070030B	MO35070040B	MO35070050B	MO35070060B	MO35070080B	MO35070120B
8.00	MO35080020B	MO35080030B	MO35080040B	MO35080050B	MO35080060B	MO35080080B	MO35080120B
9.00	MO35090020B	MO35090030B	MO35080040B	MO35090050B	MO35090060B	MO35090080B	
10.00	MO35100020B	MO35100030B	MO35100040B	MO35100050B	MO35100060B	MO35100080B	
For : Catheter with Usable length 1350 mm							

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Meril Life Sciences Pvt. Ltd. Muktanand Marg, Chala, Vapi, Gujarat, India-396191

EU Representative

Obelis S.A. Brussels, Belgium

SOCIETATEA CU RĂSPUNDERE LIMITATĂ «LIFE MED» S.R.L. IDNO 1014600035666 REPUBLICA MOLDOVA, mun. CHIȘINĂU

EC Certificate
Full Quality Assurance System

A DNV GL & NEMKO COMPANY

Certificate No.:	Project No.:	Valid Until:
11031-2017-CE-IND-NA-PS Rev. 0.0	**PRJC-57298-2008-PRC-IND**	**30 May 2018**

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

EC Certificate
Full Quality Assurance System

Certificate No.:
11110-2017-CE-IND-NA-PB Rev. 0.0

Project No.:
PRJC-67298-2008-PRC-IND

Valid Until:
12 March 2020

This is to certify that the quality system of:

Meril Life Sciences Private Limited
Muktanand Marg, Chala, Vapi,
Gujarat,
India-396191

For design, production and final product inspection/testing of:

Sterile Peripheral Stent System

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H2) of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 1 November 2017

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL-NEMKO PRESAFE AS

Alessandra Rinna

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

EC Certificate
Full Quality Assurance System

A DNV GL & NEMKO COMPANY

Certificate No.: **11119-2017-CE-IND-NA-PS Rev. 0.0**

Project No.: **PRJC-57298-2008-PRC-IND**

Valid Until: **12 March 2020**

Jurisdiction

Application of Council Directive 93/42/EEC of 14.June 1993, adopted as "Forskrift for Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Supersedes DNVGL (NB0434) certificate no 5707-2014-CE-IND-NA Rev 1.0 following transfer of notified body functions to DNV GL Nemko Presafe AS (NB2460).	2017-11-01

Products covered by this Certificate:

Product Description	Product Name	Class
Myra™ BMS – Balloon Expandable Peripheral Stent System	Myra™ BMS –Balloon Expandable Peripheral Stent System	IIb

Catalogue Numbers

Stent Diameter (mm)	Stent length (mm)				
	17	27	37	47	57
5.00	MYB05017A	MYB05027A	MYB05037A	MYB05047A	MYB05057A
6.00	MYB06017A	MYB06027A	MYB06037A	MYB06047A	MYB06057A
7.00	MYB07017A	MYB07027A	MYB07037A	MYB07047A	MYB07057A
8.00	MYB08017A	MYB08027A	MYB08037A	MYB08047A	MYB08057A
9.00	MYB09017A	MYB09027A	MYB09037A	MYB09047A	MYB09057A
10.00	MYB10017A	MYB10027A	MYB10037A	MYB10047A	MYB10057A

For usable length 800mm

SOCIETATEA CU RASPUNDERE LIMITATA «LIFE MED» S.R.L. IDNO 1014600

EC Certificate
Full Quality Assurance System

Certificate No.: **11119-2017-CE-IND-NA-PS Rev. 0.0**
Project No.: **PRJC-57298-2008-PRC-IND**
Valid Until: **12 March 2020**

Catalogue Numbers					
Stent Diameter (mm)	Stent length (mm)				
	17	27	37	47	57
5.00	MYB05017B	MYB05027B	MYB05037B	MYB05047B	MYB05057B
6.00	MYB06017B	MYB06027B	MYB06037B	MYB06047B	MYB06057B
7.00	MYB07017B	MYB07027B	MYB07037B	MYB07047B	MYB07057B
8.00	MYB08017B	MYB08027B	MYB08037B	MYB08047B	MYB08057B
9.00	MYB09017B	MYB09027B	MYB09037B	MYB09047B	MYB09057B
10.00	MYB10017B	MYB10027B	MYB10037B	MYB10047B	MYB10057B
For usable length 1350mm					

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Meril Life Sciences Pvt. Ltd. Muktanand Marg, Chala, Vapi, Gujarat, India-396191

EU Representative

Obelis S.A. Brussels, Belgium

SOCIETATEA CU RĂSPUNDERE LIMITATĂ «LIFE MED» S.R.L. IDNO 1014600035666 REPUBLICA MOLDOVA, mun. CHIȘINĂU

EC Certificate
Full Quality Assurance System

A DNV GL & NEMKO COMPANY

Certificate No.:	Project No.:	Valid Until:
11119-2017-CE-IND-NA-PS Rev. 0.0	**PRJC-57298-2008-PRC-IND**	**12 March 2020**

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

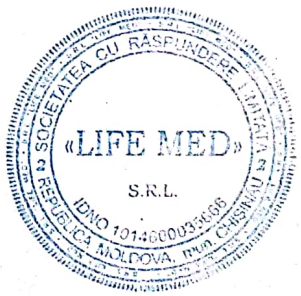
The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate



Management System Certificate

A DNV GL & NEMKO COMPANY

Certificate No.:	Project No.:	Initial Certification Date:	Valid Until:
242566-2017-AQ-IND-NA-PS Rev. 0.0	PRJC-517914-2015-MSL-IND	17 July 2008	28 February 2019

This is to certify that the management system of:

Meril Life Sciences Pvt. Ltd.
Muktanand Marg, Chala, Vapi,
Gujarat, India-396191

Complies with the requirements of:

ISO 13485:2003/NS-EN ISO 13485:2012

The Certificate is valid for the following scope:

Design, Manufacture, Sales and Distribution of Drug Eluting and Bare Metal Vascular Stents and Stent Systems, Inflation Devices, PTCA and PTA Balloon Dilatation Catheters, PTCA and PTA Guidewires, Aspiration Catheters, Sinuplasty System, Occluder and Delivery System, Angiokit, Drug Eluting PTCA and PTA Balloon Dilatation Catheters, Drug Eluting Bioresorbabale Vascular Scaffold System, Intra Aortic Balloon Catheters, Liquid Embolic System and Vascular Closure Device

«LIFE MED» S.R.L.

Place and Date:
Høvik, 12 July 2017

NORWEGIAN ACCREDITATION
MSYS 018

For:
DNV GL NEMKO PRESAFE AS

Bjørg Synnøve Nesgård

Bjørg Synnøve Nesgård

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

Date: 04th February, 2019

Letter of Authorization

We, Meril Life Sciences Pvt. Ltd. hereby authorize,

Life Med SRL
Chisinau,
30, Tudor Strisca Str.,
fiscal code: 1014600035666
Republic of Moldova,
Tel: +381 11/414-09-30

as our authorized agent representing our product range:

BioMime™- Sirolimus Eluting Coronary Stent System (Annexure A)
NexGen™- Cobalt Chromium Coronary Stent System (Annexure B)
Mozec™ NC - Rx PTCA Balloon Dilatation Catheter (Annexure C)
Mozec™ - Rx PTCA Dilatation Balloon Catheter (Annexure D)

Consisting of all products and product - sizes according to attached products lists (Annexures) for the territory of Republic of Moldova.

This document is valid up to 03rd February, 2020.

Sincerely,

Meril Life Sciences Pvt. Ltd. Vapi

«LIFE MED» S.R.L. IDNO 1014600035666 mun. CHISINAU

Sanjay Yadav
Sr. General Manager - International Sales