Meril

DECLARATION OF CONFORMITY

Manufacturer's Name: **MERIL LIFE SCIENCES PVT. LTD.**

Manufacturer's Address: Muktanand Marg, Chala, Vapi – 396191, Gujarat, India.

Product Name: **BioMime™ – Sirolimus Eluting Coronary Stent System**

Product Details:

GMDN Code:	P 58771	Control No.: RO/DOC/BIO/Rev.00	
Batch Released Quantity:	_____	Mfg. Date:	_____
Batch No.:	_____	Expiry Date:	_____

Conforms to the applicable national and international standards.
(List of UDI -DI covered by this declaration are enlisted in the Annexure -I)

1. We declare that our products as listed below, comply to the requirements to Medical device Directive 93/42/EEC as amended by directive 2007/47/EC, Commission Regulation (EU) No. 722/2012 of 8 August 2012, Annex I and this declaration is sole responsibility of company.

A. **BioMime™ – Sirolimus Eluting Coronary Stent System**

2. Company undertakes to manufacture the products as per National/ International Standards and following quality management system as per EN ISO 13485:2016 & ISO 13485:2016.
3. Company authorizes the notified body to carry out necessary inspection and agrees to supply the required information & data/documents from time to time.
4. Company agrees to make available all relevant Documents & Data of the products to the National and Competent Authority for a period ending 05 (Five) years after the last product has been manufactured.
5. Company or his authorized representative shall fulfill the obligations imposed by Annex II (Full Quality Assurance System) of Medical Device Directive 93/42/EEC as amended & ensures & declares that the Company's Products shall meet all provision of the directive as applicable.
6. Company undertakes to keep up to date a systematic procedure to review experience gained during post production phase and to implement appropriate means to apply any necessary corrective action taking account of the nature & risk in relation to the product.
7. Company undertakes to notify immediately any malfunction /deterioration of the performance of the device to the appropriate authority and shall recall such devices already placed in the market.
8. Company shall fulfill the obligations imposed by Annex I of Medical Device Directive 93/42/EEC as amended & ensures & declares that the Company's Products shall meet all provision of the directive as applicable.

List of Standard Applied:	MDD/93/42/EEC as amended by Directive 2007/47/EC, DIRECTIVE 65/65/EEC, EN ISO 13485:2016, ISO 13485:2016, EN ISO 14971:2012, EN ISO 15223-1:2016, EN 1041:2008 A1:2013, EN ISO 25539-2:2012, EN ISO 10993-1:2009, ISO 11135:2014, EN ISO 11607-1:2019, ASTM F 1980:2016.
Conformity Assessment Route:	Annex: II. of MDD/93/42/EEC on Medical Devices as amended.
Device Classification:	As per MDD/93/42/EEC of 14th June 1993, Annexure IX, Rules 8 and 13, i.e. **BioMime™ – Sirolimus Eluting Coronary Stent System** is surgically invasive and long term use (permanent implant intended for continuous use for greater than 30 days), sterile medical device, it comes in direct contact with heart and central circulatory system. It also incorporates a Medicinal Product as defined in Article 1 of Directive 65/65/EEC. Hence it is classified as class III Medical Device.
CE Certificate No.:	CE certificate no. 1434-MDD-332/2021; & EC Design Certificate No. and 1434-MDD-331/2021
CE Certificate Issue Date:	24th May, 2021
CE Certificate Valid till:	27th May, 2024
European Authorized Representative:	Obelis s.a., Bd. General Wahis 53, 1030 Brussels, Belgium. Tel: +32. 2. 732. 59. 54, Fax: +32. 2. 732. 60. 03 E-mail: mail@obelis.net
Notifying Body:	Polish Centre for Testing and Certification ul.Pulawska 469, 02-844 Warszawa, POLAND (NB 1434) Website: www.pcbc.gov.pl Phone: +48 22 46 45 200 Fax: +48 22 46 45 251
Signature:	Meril Life Sciences Pvt. Ltd. Vapi
Name:	Mr. Pratik Vasani
Designation:	AGM - Regulatory Affairs
Date/Location:	**Date:** 01-08-2022 **Location:** Vapi, Gujarat, INDIA

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

CE 1434

Meril

Annexure I - List of UDI -DI for BioMime™ – Sirolimus Eluting Coronary Stent System

Sr. No.	Product Name	UDI -DI
1.	BioMime™ – Sirolimus Eluting Coronary Stent System	89042249SECSSTY

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

CE 1434

Anexă nr 1

Către
Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr.84 din 28 septembrie 2023

Solicitantul **„Life Med"** SRL , cu sediul *mun. Chişinău, Republica Moldova str. Tudor Strişcă, 30*, tel./fax: 060807745, e-mail vlas.ion@lifemed.md , solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea şi punerea la dispoziţie pe piaţă a:

1) Stent coronarian BioMime ;

Se anexează următoarele acte:
DC in numar de 2 pagini, EC 1434-MDD-332/2021 in numar de 1 pagina, EC 1434-MDD-331/2021 în număr de 13 pagini.

Data 28.09.2023 Semnătura

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

Tabelul de recepţionare a notificării
(se completează de către Agenţie în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepţionării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenţie (în cazul acceptării recepţionării)	
Numele, prenumele, funcţia persoanei responsabile de recepţionarea dosarului	
Semnătura persoanei responsabile	

Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului şi Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: "Life MED" SRL , cu sediul *mun. Chișinău, Republica Moldova*

str. Tudor Strișcă, 30,declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

1) Stent Coronarian BioMime

Sunt autentice și corespund realităţii.

Numele, prenumele şi funcţia

Administrator Railean Efimia

Semnătura _____

Data 28.09.2023

CERTIFICATE

EC Certificate No. 1434-MDD-331/2021

EC Design-examination

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the documentation submitted by:

Meril Life Sciences Pvt. Ltd.

Muktanand Marg, Chala, Vapi-396191, Gujarat, India

related to the medical device, class III

BioMime™ Sirolimus Eluting Coronary Stent System

The list of medical devices covered by this certificate is provided in the annexes 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 and 12

was examined in accordance with Annex II (Section 4) to Directive 93/42/EEC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 24/05/2024 to 27/05/2024

The date of issue of the Certificate: 24/05/2021

The date of the first issue of the Certificate: 26/07/2019

CE 1434

Issued under the Contract No. MD-131/2019
Application No: 030/2021
Certificate bears the qualified signature.
Warsaw, 24/05/2021
Module H1

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

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.05.24 09:57:13 +02'00'

Anna Wyroba
Vice-President

ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-331/2021

List of medical devices covered by the certificate:

BioMime™ – Sirolimus Eluting Coronary Stent System											
Diameter (mm)	Length (mm)										
	8	13	16	19	24	29	32	37	40	44	48
2.00	-	BIO20013	BIO20016	BIO20019	BIO20024	BIO20029	BIO20032	BIO20037	BIO20040	BIO20044	BIO20048
2.25	BIO22508	BIO22513	BIO22516	BIO22519	BIO22524	BIO22529	BIO22532	BIO22537	BIO22540	BIO22544	BIO22548
2.50	BIO25008	BIO25013	BIO25016	BIO25019	BIO25024	BIO25029	BIO25032	BIO25037	BIO25040	BIO25044	BIO25048
2.75	BIO27508	BIO27513	BIO27516	BIO27519	BIO27524	BIO27529	BIO27532	BIO27537	BIO27540	BIO27544	BIO27548
3.00	BIO30008	BIO30013	BIO30016	BIO30019	BIO30024	BIO30029	BIO30032	BIO30037	BIO30040	BIO30044	BIO30048
3.50	BIO35008	BIO35013	BIO35016	BIO35019	BIO35024	BIO35029	BIO35032	BIO35037	BIO35040	BIO35044	BIO35048
4.00	BIO40008	BIO40013	BIO40016	BIO40019	BIO40024	BIO40029	BIO40032	BIO40037	BIO40040	BIO40044	BIO40048
4.50	BIO45008	BIO45013	BIO45016	BIO45019	BIO45024	BIO45029	BIO45032	BIO45037	BIO45040	BIO45044	BIO45048

CE 1434

Issued under the Contract No. MD-131/2019
Application No: 030/2021
Certificate bears the qualified signature.
Warsaw, 24/05/2021

«LIFE MED» S.R.L. IDNO 1014600035666

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.05.24 09:46:55 +02'00'

Anna Wyroba
Vice-President

ANNEX 2 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-331/2021

List of medical devices covered by the certificate:

BioMime™ – Sirolimus Eluting Coronary Stent System (Model 2)

Diameter (mm)	Length (mm)										
	8	13	16	19	24	29	32	37	40	44	48
2.00	-	BIO220013	BIO220016	BIO220019	BIO220024	BIO220029	BIO220032	BIO220037	BIO220040	BIO220044	BIO220048
2.25	BIO222508	BIO222513	BIO222516	BIO222519	BIO222524	BIO222529	BIO222532	BIO222537	BIO222540	BIO222544	BIO222548
2.50	BIO225008	BIO225013	BIO225016	BIO225019	BIO225024	BIO225029	BIO225032	BIO225037	BIO225040	BIO225044	BIO225048
2.75	BIO227508	BIO227513	BIO227516	BIO227519	BIO227524	BIO227529	BIO227532	BIO227537	BIO227540	BIO227544	BIO227548
3.00	BIO230008	BIO230013	BIO230016	BIO230019	BIO230024	BIO230029	BIO230032	BIO230037	BIO230040	BIO230044	BIO230048
3.50	BIO235008	BIO235013	BIO235016	BIO235019	BIO235024	BIO235029	BIO235032	BIO235037	BIO235040	BIO235044	BIO235048
4.00	BIO240008	BIO240013	BIO240016	BIO240019	BIO240024	BIO240029	BIO240032	BIO240037	BIO240040	BIO240044	BIO240048
4.50	BIO245008	BIO245013	BIO245016	BIO245019	BIO245024	BIO245029	BIO245032	BIO245037	BIO245040	BIO245044	BIO245048

CE 1434

Issued under the Contract No. MD-131/2019
Application No: 030/2021
Certificate bears the qualified signature.
Warsaw, 24/05/2021

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.05.24 09:48:00 +02'00'

Anna Wyroba
Vice-President

ANNEX 3 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-331/2021

List of medical devices covered by the certificate:

BioMime Aura™ – Sirolimus Eluting Coronary Stent System											
Diameter (mm)	Length (mm)										
	8	13	16	19	24	29	32	37	40	44	48
2.00	-	BIA20013	BIA20016	BIA20019	BIA20024	BIA20029	BIA20032	BIA20037	BIA20040	BIA20044	BIA20048
2.25	BIA22508	BIA22513	BIA22516	BIA22519	BIA22524	BIA22529	BIA22532	BIA22537	BIA22540	BIA22544	BIA22548
2.50	BIA25008	BIA25013	BIA25016	BIA25019	BIA25024	BIA25029	BIA25032	BIA25037	BIA25040	BIA25044	BIA25048
2.75	BIA27508	BIA27513	BIA27516	BIA27519	BIA27524	BIA27529	BIA27532	BIA27537	BIA27540	BIA27544	BIA27548
3.00	BIA30008	BIA30013	BIA30016	BIA30019	BIA30024	BIA30029	BIA30032	BIA30037	BIA30040	BIA30044	BIA30048
3.50	BIA35008	BIA35013	BIA35016	BIA35019	BIA35024	BIA35029	BIA35032	BIA35037	BIA35040	BIA35044	BIA35048
4.00	BIA40008	BIA40013	BIA40016	BIA40019	BIA40024	BIA40029	BIA40032	BIA40037	BIA40040	BIA40044	BIA40048
4.50	BIA45008	BIA45013	BIA45016	BIA45019	BIA45024	BIA45029	BIA45032	BIA45037	BIA45040	BIA45044	BIA45048

CE 1434

Issued under the Contract No. MD-131/2019
Application No: 030/2021
Certificate bears the qualified signature.
Warsaw, 24/05/2021

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.05.24 09:48:48 +02'00'

Anna Wyroba
Vice-President

ANNEX 4 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-331/2021

List of medical devices covered by the certificate:

BioMime Aura™ – Sirolimus Eluting Coronary Stent System (Model 2)											
Diameter (mm)	Length (mm)										
	8	13	16	19	24	29	32	37	40	44	48
2.00	-	BIA220013	BIA220016	BIA220019	BIA220024	BIA220029	BIA220032	BIA220037	BIA220040	BIA220044	BIA220048
2.25	BIA222508	BIA222513	BIA222516	BIA222519	BIA222524	BIA222529	BIA222532	BIA222537	BIA222540	BIA222544	BIA222548
2.50	BIA225008	BIA225013	BIA225016	BIA225019	BIA225024	BIA225029	BIA225032	BIA225037	BIA225040	BIA225044	BIA225048
2.75	BIA227508	BIA227513	BIA227516	BIA227519	BIA227524	BIA227529	BIA227532	BIA227537	BIA227540	BIA227544	BIA227548
3.00	BIA230008	BIA230013	BIA230016	BIA230019	BIA230024	BIA230029	BIA230032	BIA230037	BIA230040	BIA230044	BIA230048
3.50	BIA235008	BIA235013	BIA235016	BIA235019	BIA235024	BIA235029	BIA235032	BIA235037	BIA235040	BIA235044	BIA235048
4.00	BIA240008	BIA240013	BIA240016	BIA240019	BIA240024	BIA240029	BIA240032	BIA240037	BIA240040	BIA240044	BIA240048
4.50	BIA245008	BIA245013	BIA245016	BIA245019	BIA245024	BIA245029	BIA245032	BIA245037	BIA245040	BIA245044	BIA245048

CE 1434

«LIFE MED» S.R.L. IDNO 1014600035666

Issued under the Contract No. MD-131/2019
Application No: 030/2021
Certificate bears the qualified signature.
Warsaw, 24/05/2021

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.05.24 09:49:39 +02'00'

Anna Wyroba
Vice-President

ANNEX 5 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-331/2021

List of medical devices covered by the certificate:

Metafor™ – Sirolimus Eluting Coronary Stent System											
Diameter (mm)	Length (mm)										
	8	13	16	19	24	29	32	37	40	44	48
2.00	-	MTR20013	MTR20016	MTR20019	MTR20024	MTR20029	MTR20032	MTR20037	MTR20040	MTR20044	MTR20048
2.25	MTR22508	MTR22513	MTR22516	MTR22519	MTR22524	MTR22529	MTR22532	MTR22537	MTR22540	MTR22544	MTR22548
2.50	MTR25008	MTR25013	MTR25016	MTR25019	MTR25024	MTR25029	MTR25032	MTR25037	MTR25040	MTR25044	MTR25048
2.75	MTR27508	MTR27513	MTR27516	MTR27519	MTR27524	MTR27529	MTR27532	MTR27537	MTR27540	MTR27544	MTR27548
3.00	MTR30008	MTR30013	MTR30016	MTR30019	MTR30024	MTR30029	MTR30032	MTR30037	MTR30040	MTR30044	MTR30048
3.50	MTR35008	MTR35013	MTR35016	MTR35019	MTR35024	MTR35029	MTR35032	MTR35037	MTR35040	MTR35044	MTR35048
4.00	MTR40008	MTR40013	MTR40016	MTR40019	MTR40024	MTR40029	MTR40032	MTR40037	MTR40040	MTR40044	MTR40048
4.50	MTR45008	MTR45013	MTR45016	MTR45019	MTR45024	MTR45029	MTR45032	MTR45037	MTR45040	MTR45044	MTR45048

CE 1434

Issued under the Contract No. MD-131/2019
Application No: 030/2021
Certificate bears the qualified signature.
Warsaw, 24/05/2021

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.05.24 09:50:24 +02'00'

Anna Wyroba
Vice-President

ANNEX 6 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-331/2021

List of medical devices covered by the certificate:

Metafor™ – Sirolimus Eluting Coronary Stent System (Model 2)

Diameter (mm)	Length (mm)										
	8	13	16	19	24	29	32	37	40	44	48
2.00	-	MTR220013	MTR220016	MTR220019	MTR220024	MTR220029	MTR220032	MTR220037	MTR220040	MTR220044	MTR220048
2.25	MTR222508	MTR222513	MTR222516	MTR222519	MTR222524	MTR222529	MTR222532	MTR222537	MTR222540	MTR222544	MTR222548
2.50	MTR225008	MTR225013	MTR225016	MTR225019	MTR225024	MTR225029	MTR225032	MTR225037	MTR225040	MTR225044	MTR225048
2.75	MTR227508	MTR227513	MTR227516	MTR227519	MTR227524	MTR227529	MTR227532	MTR227537	MTR227540	MTR227544	MTR227548
3.00	MTR230008	MTR230013	MTR230016	MTR230019	MTR230024	MTR230029	MTR230032	MTR230037	MTR230040	MTR230044	MTR230048
3.50	MTR235008	MTR235013	MTR235016	MTR235019	MTR235024	MTR235029	MTR235032	MTR235037	MTR235040	MTR235044	MTR235048
4.00	MTR240008	MTR240013	MTR240016	MTR240019	MTR240024	MTR240029	MTR240032	MTR240037	MTR240040	MTR240044	MTR240048
4.50	MTR245008	MTR245013	MTR245016	MTR245019	MTR245024	MTR245029	MTR245032	MTR245037	MTR245040	MTR245044	MTR245048

CE 1434

Issued under the Contract No. MD-131/2019
Application No: 030/2021
Certificate bears the qualified signature.
Warsaw, 24/05/2021

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.05.24 09:51:14 +02'00'

Anna Wyroba
Vice-President

ANNEX 7 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-331/2021

List of medical devices covered by the certificate:

Proficient™ – Sirolimus Eluting Coronary Stent System											
Diameter (mm)	Length (mm)										
	8	13	16	19	24	29	32	37	40	44	48
2.00	-	PRF20013	PRF20016	PRF20019	PRF20024	PRF20029	PRF20032	PRF20037	PRF20040	PRF20044	PRF20048
2.25	PRF22508	PRF22513	PRF22516	PRF22519	PRF22524	PRF22529	PRF22532	PRF22537	PRF22540	PRF22544	PRF22548
2.50	PRF25008	PRF25013	PRF25016	PRF25019	PRF25024	PRF25029	PRF25032	PRF25037	PRF25040	PRF25044	PRF25048
2.75	PRF27508	PRF27513	PRF27516	PRF27519	PRF27524	PRF27529	PRF27532	PRF27537	PRF27540	PRF27544	PRF27548
3.00	PRF30008	PRF30013	PRF30016	PRF30019	PRF30024	PRF30029	PRF30032	PRF30037	PRF30040	PRF30044	PRF30048
3.50	PRF35008	PRF35013	PRF35016	PRF35019	PRF35024	PRF35029	PRF35032	PRF35037	PRF35040	PRF35044	PRF35048
4.00	PRF40008	PRF40013	PRF40016	PRF40019	PRF40024	PRF40029	PRF40032	PRF40037	PRF40040	PRF40044	PRF40048
4.50	PRF45008	PRF45013	PRF45016	PRF45019	PRF45024	PRF45029	PRF45032	PRF45037	PRF45040	PRF45044	PRF45048

CE 1434

«LIFE MED» S.R.L. IDNO 1014600035666 MOLDOVA, mun. CHIȘINĂU

Issued under the Contract No. MD-131/2019
Application No: 030/2021
Certificate bears the qualified signature.
Warsaw, 24/05/2021

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.05.24 09:52:06 +02'00'

Anna Wyroba
Vice-President

ANNEX 8 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-331/2021

List of medical devices covered by the certificate:

Proficient™ – Sirolimus Eluting Coronary Stent System (Model 2)											
Diameter (mm)	Length (mm)										
	8	13	16	19	24	29	32	37	40	44	48
2.00	-	PRF220013	PRF220016	PRF220019	PRF220024	PRF220029	PRF220032	PRF220037	PRF220040	PRF220044	PRF220048
2.25	PRF222508	PRF222513	PRF222516	PRF222519	PRF222524	PRF222529	PRF222532	PRF222537	PRF222540	PRF222544	PRF222548
2.50	PRF225008	PRF225013	PRF225016	PRF225019	PRF225024	PRF225029	PRF225032	PRF225037	PRF225040	PRF225044	PRF225048
2.75	PRF227508	PRF227513	PRF227516	PRF227519	PRF227524	PRF227529	PRF227532	PRF227537	PRF227540	PRF227544	PRF227548
3.00	PRF230008	PRF230013	PRF230016	PRF230019	PRF230024	PRF230029	PRF230032	PRF230037	PRF230040	PRF230044	PRF230048
3.50	PRF235008	PRF235013	PRF235016	PRF235019	PRF235024	PRF235029	PRF235032	PRF235037	PRF235040	PRF235044	PRF235048
4.00	PRF240008	PRF240013	PRF240016	PRF240019	PRF240024	PRF240029	PRF240032	PRF240037	PRF240040	PRF240044	PRF240048
4.50	PRF245008	PRF245013	PRF245016	PRF245019	PRF245024	PRF245029	PRF245032	PRF245037	PRF245040	PRF245044	PRF245048

CE 1434

Issued under the Contract No. MD-131/2019
Application No: 030/2021
Certificate bears the qualified signature.
Warsaw, 24/05/2021

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

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.05.24 09:52:57 +02'00'

Anna Wyroba
Vice-President

ANNEX 9 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-331/2021

List of medical devices covered by the certificate:

BioMime Lineage™ – Sirolimus Eluting Coronary Stent System											
Diameter (mm)	Length (mm)										
	8	13	16	19	24	29	32	37	40	44	48
2.00	-	BIL20013	BIL20016	BIL20019	BIL20024	BIL20029	BIL20032	BIL20037	BIL20040	BIL20044	BIL20048
2.25	BIL22508	BIL22513	BIL22516	BIL22519	BIL22524	BIL22529	BIL22532	BIL22537	BIL22540	BIL22544	BIL22548
2.50	BIL25008	BIL25013	BIL25016	BIL25019	BIL25024	BIL25029	BIL25032	BIL25037	BIL25040	BIL25044	BIL25048
2.75	BIL27508	BIL27513	BIL27516	BIL27519	BIL27524	BIL27529	BIL27532	BIL27537	BIL27540	BIL27544	BIL27548
3.00	BIL30008	BIL30013	BIL30016	BIL30019	BIL30024	BIL30029	BIL30032	BIL30037	BIL30040	BIL30044	BIL30048
3.50	BIL35008	BIL35013	BIL35016	BIL35019	BIL35024	BIL35029	BIL35032	BIL35037	BIL35040	BIL35044	BIL35048
4.00	BIL40008	BIL40013	BIL40016	BIL40019	BIL40024	BIL40029	BIL40032	BIL40037	BIL40040	BIL40044	BIL40048
4.50	BIL45008	BIL45013	BIL45016	BIL45019	BIL45024	BIL45029	BIL45032	BIL45037	BIL45040	BIL45044	BIL45048

CE 1434

Issued under the Contract No. MD-131/2019
Application No: 030/2021
Certificate bears the qualified signature.
Warsaw, 24/05/2021

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

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.05.24 09:53:53 +02'00'

Anna Wyroba
Vice-President

ANNEX 10 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-331/2021

List of medical devices covered by the certificate:

BioMime Lineage™ – Sirolimus Eluting Coronary Stent System (Model 2)

Diameter (mm)	Length (mm)										
	8	13	16	19	24	29	32	37	40	44	48
2.00	-	BIL220013	BIL220016	BIL220019	BIL220024	BIL220029	BIL220032	BIL220037	BIL220040	BIL220044	BIL220048
2.25	BIL222508	BIL222513	BIL222516	BIL222519	BIL222524	BIL222529	BIL222532	BIL222537	BIL222540	BIL222544	BIL222548
2.50	BIL225008	BIL225013	BIL225016	BIL225019	BIL225024	BIL225029	BIL225032	BIL225037	BIL225040	BIL225044	BIL225048
2.75	BIL227508	BIL227513	BIL227516	BIL227519	BIL227524	BIL227529	BIL227532	BIL227537	BIL227540	BIL227544	BIL227548
3.00	BIL230008	BIL230013	BIL230016	BIL230019	BIL230024	BIL230029	BIL230032	BIL230037	BIL230040	BIL230044	BIL230048
3.50	BIL235008	BIL235013	BIL235016	BIL235019	BIL235024	BIL235029	BIL235032	BIL235037	BIL235040	BIL235044	BIL235048
4.00	BIL240008	BIL240013	BIL240016	BIL240019	BIL240024	BIL240029	BIL240032	BIL240037	BIL240040	BIL240044	BIL240048
4.50	BIL245008	BIL245013	BIL245016	BIL245019	BIL245024	BIL245029	BIL245032	BIL245037	BIL245040	BIL245044	BIL245048

CE 1434

Issued under the Contract No. MD-131/2019
Application No: 030/2021
Certificate bears the qualified signature.
Warsaw, 24/05/2021

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.05.24 09:54:45 +02'00'

Anna Wyroba
Vice-President

ANNEX 11 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-331/2021

List of medical devices covered by the certificate:

Prevade™ – Sirolimus Eluting Coronary Stent System											
Diameter (mm)	Length (mm)										
	8	13	16	19	24	29	32	37	40	44	48
2.00	-	PRV20013	PRV20016	PRV20019	PRV20024	PRV20029	PRV20032	PRV20037	PRV20040	PRV20044	PRV20048
2.25	PRV22508	PRV22513	PRV22516	PRV22519	PRV22524	PRV22529	PRV22532	PRV22537	PRV22540	PRV22544	PRV22548
2.50	PRV25008	PRV25013	PRV25016	PRV25019	PRV25024	PRV25029	PRV25032	PRV25037	PRV25040	PRV25044	PRV25048
2.75	PRV27508	PRV27513	PRV27516	PRV27519	PRV27524	PRV27529	PRV27532	PRV27537	PRV27540	PRV27544	PRV27548
3.00	PRV30008	PRV30013	PRV30016	PRV30019	PRV30024	PRV30029	PRV30032	PRV30037	PRV30040	PRV30044	PRV30048
3.50	PRV35008	PRV35013	PRV35016	PRV35019	PRV35024	PRV35029	PRV35032	PRV35037	PRV35040	PRV35044	PRV35048
4.00	PRV40008	PRV40013	PRV40016	PRV40019	PRV40024	PRV40029	PRV40032	PRV40037	PRV40040	PRV40044	PRV40048
4.50	PRV45008	PRV45013	PRV45016	PRV45019	PRV45024	PRV45029	PRV45032	PRV45037	PRV45040	PRV45044	PRV45048

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

CE 1434

Issued under the Contract No. MD-131/2019
Application No: 030/2021
Certificate bears the qualified signature.
Warsaw, 24/05/2021

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.05.24 09:55:31 +02'00'

Anna Wyroba
Vice-President

ANNEX 12 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-331/2021

List of medical devices covered by the certificate:

Prevade™ – Sirolimus Eluting Coronary Stent System (Model 2)											
Diameter (mm)	Length (mm)										
	8	13	16	19	24	29	32	37	40	44	48
2.00	-	PRV220013	PRV220016	PRV220019	PRV220024	PRV220029	PRV220032	PRV220037	PRV220040	PRV220044	PRV220048
2.25	PRV222508	PRV222513	PRV222516	PRV222519	PRV222524	PRV222529	PRV222532	PRV222537	PRV222540	PRV222544	PRV222548
2.50	PRV225008	PRV225013	PRV225016	PRV225019	PRV225024	PRV225029	PRV225032	PRV225037	PRV225040	PRV225044	PRV225048
2.75	PRV227508	PRV227513	PRV227516	PRV227519	PRV227524	PRV227529	PRV227532	PRV227537	PRV227540	PRV227544	PRV227548
3.00	PRV230008	PRV230013	PRV230016	PRV230019	PRV230024	PRV230029	PRV230032	PRV230037	PRV230040	PRV230044	PRV230048
3.50	PRV235008	PRV235013	PRV235016	PRV235019	PRV235024	PRV235029	PRV235032	PRV235037	PRV235040	PRV235044	PRV235048
4.00	PRV240008	PRV240013	PRV240016	PRV240019	PRV240024	PRV240029	PRV240032	PRV240037	PRV240040	PRV240044	PRV240048
4.50	PRV245008	PRV245013	PRV245016	PRV245019	PRV245024	PRV245029	PRV245032	PRV245037	PRV245040	PRV245044	PRV245048

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

CE 1434

Issued under the Contract No. MD-131/2019
Application No: 030/2021
Certificate bears the qualified signature.
Warsaw, 24/05/2021

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.05.24 09:56:21 +02'00'

Anna Wyroba
Vice-President

CERTIFICATE

EC Certificate No. 1434-MDD-332/2021

Full Quality Assurance System
Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Meril Life Sciences Pvt. Ltd.

Muktanand Marg, Chala, Vapi-396191, Gujarat, India

for the design, manufacture and final inspection of
medical devices, class III

BioMime™ Sirolimus Eluting Coronary Stent System

The list of medical devices covered by this certificate is provided in the annexes 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 and 12 to EC Design-examination Certificate No. 1434-MDD-331/2021

complies with requirements
of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 24/05/2021 to 27/05/2024

The date of issue of the Certificate: 24/05/2021

The date of the first issue of the Certificate: 26/07/2019

CE 1434

«LIFE MED» S.R.L. IDNO 1014600035666

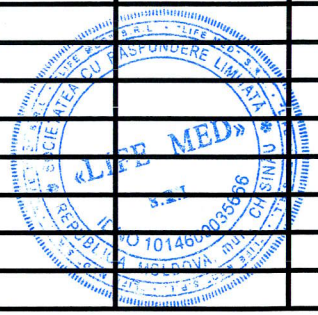
Issued under the Contract No. MD-131/2019
Application No: 030/2021
Certificate bears the qualified signature.
Warsaw, 24/05/2021
Module H2/3/4/5

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.05.24 09:58:01 +02'00'

Anna Wyroba
Vice-President

Numarul de catalog	Denumire	Denumirea comerciala	Modelul	Tip dispozitiv	Cod GMDN
BIO20013	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.00*13		
BIO20016	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.00*16		
BIO20019	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.00*19		
BIO20024	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.00*24		
BIO20029	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.00*29		
BIO20032	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.00*32		
BIO20037	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.00*37		
BIO20040	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.00*40		
BIO20044	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.00*44		
BIO20048	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.00*48		
BIO22508	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.25*08		
BIO22513	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.25*13		
BIO22516	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.25*16		
BIO22519	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.25*19		
BIO22524	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.25*24		
BIO22529	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.25*29		
BIO22532	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.25*32		
BIO22537	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.25*37		
BIO22540	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.25*40		
BIO22544	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.25*44		
BIO22548	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.25*48		
BIO25008	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.50*08		
BIO25013	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.50*13		
BIO25016	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.50*16		
BIO25019	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.50*19		
BIO25024	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.50*24		
BIO25029	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.50*29		
BIO25032	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.50*32		
BIO25037	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.50*37		
BIO25040	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.50*40		
BIO25044	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.50*44		
BIO25048	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.50*48		
BIO27508	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.75*08		



BIO27513	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.75*13		
BIO27516	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.75*16		
BIO27519	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.75*19		
BIO27524	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.75*24		
BIO27529	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.75*29		
BIO27532	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.75*32		
BIO27537	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.75*37		
BIO27540	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.75*40		
BIO27544	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.75*44		
BIO27548	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	2.75*48		
BIO30008	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	3.00*08		
BIO30013	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	3.00*13		
BIO30016	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	3.00*16		
BIO30019	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	3.00*19		
BIO30024	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	3.00*24		
BIO30029	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	3.00*29		
BIO30032	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	3.00*32		
BIO30037	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	3.00*37		
BIO30040	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	3.00*40		
BIO30044	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	3.00*44		
BIO30048	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	3.00*48		
BIO35008	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	3.50*08		
BIO35013	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	3.50*13		
BIO35016	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	3.50*16		
BIO35019	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	3.50*19		
BIO35024	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	3.50*24		
BIO35029	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	3.50*29		
BIO35032	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	3.50*32		
BIO35037	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	3.50*37		
BIO35040	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	3.50*40		
BIO35044	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	3.50*44		
BIO35048	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	3.50*48		
BIO40008	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	4.00*08		
BIO40013	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	4.00*13		

BIO40016	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	4.00*16		
BIO40019	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	4.00*19		
BIO40024	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	4.00*24		
BIO40029	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	4.00*29		
BIO40032	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	4.00*32		
BIO40037	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	4.00*37		
BIO40040	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	4.00*40		
BIO40044	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	4.00*44		
BIO40048	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	4.00*48		
BIO45008	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	4.50*08		
BIO45013	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	4.50*13		
BIO45016	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	4.50*16		
BIO45019	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	4.50*19		
BIO45024	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	4.50*24		
BIO45029	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	4.50*29		
BIO45032	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	4.50*32		
BIO45037	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	4.50*37		
BIO45040	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	4.50*40		
BIO45044	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	4.50*44		
BIO45048	Stent Coronarian cu substanta activa Sirolimus	BioMime - Sirolimus Eluting Coronary Stent System	4.50*48		

International Distributor Agreement

This Distributor Agreement (the "Agreement") is entered into on 1st November 2022 (Effective date) by and between

Meril Life Sciences Pvt. Ltd. a company registered under the provision of Indian Companies Act, 1956 having Corporate Identification No. U24119GJ2006PTC048361 and having its registered office at Survey No.135/139, Bilakhia House, Muktanand Marg, Chala, Vapi-396 191, Gujarat, India (hereinafter referred to as the "**Company**" or "**Meril**"), and

Lifemed SRL, a company registered under the provision of Republic of Moldova having Registration Number: IDNO-1014600035666 and its Place of Business at, 30 Str. Tudor Strisca, Chisinau, Zip Code 2048, Republic of Moldova (hereinafter referred to as the "**Distributor**"/ "**Lifemed**").

WHEREAS, Company is in the business of developing, manufacturing and selling medical devices (the "Products", as defined in EXHIBIT "A" attached to this agreement); and

WHEREAS, Company wishes to appoint Distributors to sell and distribute the Product in Territory as referred in the EXHIBIT "B".

AND WHEREAS the Distributor has expressed its desire to be appointed as Distributor for the territory defined below. In consideration of their mutual covenants, the parties have agreed on the terms and conditions contained in this Agreement.

NOW THEREFORE, in consideration of the mutual covenants and promises set out below, the parties hereto agree as follows-

1. Appointment

The Company appoints Lifemed as its non exclusive distributor, within the territory specified in Exhibit B attached to this Agreement (the "Territory"), subject to the terms and conditions of this Agreement.

1.1 Distributor is entitled is entitled to sell the products specified in Exhibit A attached to this Agreement (the "Products") in the Territory subject to approval by the Company. But the Distributor is not entitled to resell any samples, demonstration product, or promotional materials. Any Sales outside the defined Territory of the Distributor will not be included in the [illegible] objectives of the Distributor.

1.2 The Company reserves the right to:

a) Change the boundaries of the Territory of the Distributor by giving thirty (30) days written notice if Distributor fails to meet its sales quotas;

b) Engage in selling and promoting the Products in the Territory in the event that Distributor is unable to provide sales services as outlined herein for a consecutive period of thirty (30) days or more;

c) Add to or delete from its product line from time to time provided it is mutually agreeable to both Company and Distributor; and

d) Withdraw specific Products from the coverage of this Agreement upon ninety (90) days written notice if Distributor is unable to provide sales services for a product as outlined herein or if the specific Product is being withdrawn from the Distributor's country of operation.

1.3 The parties acknowledge that the Effective Date as set out above is the date upon which this Agreement becomes effective, but that Products may not be available for sale until a later date. The parties therefore agree that the terms and conditions of this Agreement shall remain in full force and effect from the Effective Date but that Company has no obligation to provide Products to Distributor hereunder until such time as the product is approved and/or cleared for use by the appropriate regulatory agencies or any extended time thereafter.

2. Duties and Obligations of Distributor

2.1 Distributor will carry sufficient quantity of relevant sizes product at the commencement of Distributorship business equivalent to projected next 3 months sale and will continue to replenish the stock on a monthly basis to cover next three months' projected sales volume. In addition, the distributor:

(a) Will use its best efforts to promote and solicit orders for the Products to Customers located within the Territory

(b) Provide marketing and service support to Customers, including hospitals and qualified doctors who purchase or use the Products

(c) Will be arranging in the appropriate areas of the operating room, to provide the Products and instrumentation associated with the Products

(d) Will assist the Company in training Customers, including doctors and hospital staff members, on the proper uses of the Products

(e) Will render reasonable assistance to the Company in the defense of any and all product liability claims.

(f) Will assist the Company in effectuating any recall of the Products in the Territory.

(g) Will promptly report to the Company, but in no event later than twenty four (24) hours after receipt, of any complaints or operational problems with the Products reported by Customers.

(h) Will provide and maintain, at it's own expense, one or more suitable places of business in the Territory.

(i) Will maintain a staff of individuals who are thoroughly familiar with the Products enabling them to aggressively promote and sell Products for the Company in the Territory.

(j) Will bear all costs and liabilities relating to the conduct of its business including, but not limited to, the cost and expense of providing and maintaining its place of business, the wages of its employees, the payment of commissions or other compensation to its employees or contractors, and its expenses incurred for or in connection with its performance under this Agreement.

(k) Will not modify Products or Product packaging in any way.

(l) Will indemnify, protect and hold Company, its Affiliates (as defined below) and all officers, directors, employees and agents thereof (hereinafter referred to as "Indemnities") harmless from all claims, demands, suits or actions (including attorneys' fees incurred in connection therewith) which may be asserted against Company for any kind of damages, including but without limiting to damage or injury to property or persons and all incidental and consequential damages, which may be sustained by any third party or any of the Indemnities arising out of or incidental to the conduct of Distributor's operations under this Agreement. For the purpose of this Agreement, "Affiliate" shall mean, with respect to a party, any company, natural person, partnership or other business entity that controls, is controlled by, or is under common control with such party, where the term "controls" denotes the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of an entity, or the possession, directly or indirectly, of the power to direct the management or policies of an entity, whether through the ownership of voting securities, by contract, or otherwise (with correlative definitions for the terms "controlled by" and

"common control").

(m) Will refrain from making any representations or warranties with respect to the Products, except those representations and warranties authorized in writing and will indemnify and hold the Company harmless against any liability for any claims, damages, taxes, attorneys' fees and costs incurred if such liability arises from Distributor's non-compliance with Clause 2 (l) stated above.

(n) Will comply with all applicable laws and regulations in force in the Territory and will conduct all of its business activities hereunder in accordance with generally recognized ethical standards.

(o) Will comply with all applicable Company policies and procedures including without limitation any and all compliance training and related requirements, as well as all policies and procedures governing the relationship between sales personnel and Customers.

(p) Will refrain from disparaging the Company or its Products or from otherwise injuring the reputation and good standing of the Company.

(q) Will notify the Company immediately but not later than two (2) business days after receipt of such request or demand in writing of the nature and scope of any request or demand to disclose any books, documents or records relevant to this Agreement for the purpose of an audit or investigation, or if the Distributor is contacted by any governmental agency relative to Distributor's provision of services for the Company.

(r) In the event of a Product recall, governmental inquiry, or reasonable belief that this contract is being violated, will permit the Company, at any time and during regular business hours, to audit the books and records of Distributor relevant to this Agreement and to interview any employee or sales representative of Distributor to ensure that Distributor has complied with all material terms and conditions hereof including, but not limited to, those relating to compliance with federal, state and local laws and regulations, maintenance in force of insurance policies, and maintenance of required licenses, permits and authorizations. Company shall provide Distributor with ten (10) days of notice of its intent to conduct activities pursuant to this clause 2(r). Nothing herein will be deemed as a right of the Company to review any financial records of Distributor not directly [illegible] Distributor's performance under this Agreement.

(s) Will, at all times during the term of this Agreement maintain in force, at its sole expense, commercially reasonable levels of general liability insurance, property damage insurance and comprehensive public and motor vehicle liability insurance against claims arising from its business and its activities under this Agreement

(t) Shall ensure that, while the device is under their responsibility, storage or transport conditions should comply with the conditions set by the Company.

2.2 Distributor will comply with all governmental laws, regulations and requirements applicable to the duties conducted hereunder and applicable medical devices, including, without limitation, under respective laws of land in force from time to time and will keep accurate records of inventory.

2.3 If Distributor receives any order from a prospective purchaser whose principal place of business is located outside the Territory, Distributor shall immediately refer that order to Company. Distributor shall not accept any such orders. Distributor may not deliver or tender (or cause to be delivered or tendered) any Product outside of the Territory.

2.4 Distributor shall employ competent and experienced service personnel, provide appropriate facilities and resources, provide adequate and appropriate training to its staff concerning the product and its applications so as to render prompt and adequate service to the users of the Product in the Territory in accordance with all of Distributor's obligations under this Agreement.

2.5 Distributor shall make legitimate use of sales and technical literature as well as promotional artwork and training materials provided by Company. Distributor may alter such materials or develop any other materials in connection with the marketing and distribution of the Product (including but not limited to product brochures and sales aids), subject to Company's review and written approval prior to any use of such materials. Company shall retain all right, title and interest in all such original, altered or other materials developed by Distributor in relation to company's products.

2.6 Distributor shall provide customer service (including, but not limited to, taking orders, responding to customer inquiries, fulfilling requests for quotes on Product pricing, and forwarding Product complaints to Company as legally required) on a timely basis and shall provide such assistance and information to customers as is reasonably requested by Company.

2.7 Distributor represents and warrants that at present and during the term of the Agreement, Distributor and its owners, principals, employees and/or contractors:

a) have not been and will not be sanctioned under the respective laws of the land in force from time to time;

b) have not had and will not have a complaint filed against Distributor by any enforcement agency; and

c) have not engaged and will not engage in any conduct that could give rise to sanctions, convictions, or violations of any of the identified laws; and

d) are free to enter into this relationship with Company and that by doing so, is not violating and will not violate any agreement or understanding, written or unwritten, with any third party.

e) In the event of Distributor becoming aware of the debarment or disqualification of any person providing services to Distributor as mentioned above or otherwise, Distributor shall forthwith notify Company.

2.8 Distributor represents and warrants that Distributor shall have in effect at all times during the Initial Term and any Renewal Terms of this Agreement all licenses, permits, and authorizations from all federal, state, and local authorities necessary to the performance of Distributor's obligations under this Agreement and all necessary authorization to enter patient care areas of each hospital in its Territory where such access is necessary.

2.9 Distributor and its individual owners, principals, employees and/or contractors shall comply with Company's codes of conducts, policies and procedures (collectively "Policies"). In the event of any conflict between such Policies and this Agreement, the terms of this Agreement shall prevail.

2.10 Distributor will carry out product registration, approvals of local government authorities in name of the Company from time to time as instructed by the Company. The cost shall be borne by the Company.

a) In the event of termination of Distributor's rights for any reason, Distributor agrees to transfer free of charge to Company or to any person or corporation designated by Company all the Health Regulatory Approvals. All the fees of the Health Regulatory Approvals as regard to the transfer will be entirely borne by Company.

b) Even if the Health Regulatory Approvals shall be held by Distributor, they will remain the property of Company.

c) In the event of termination of Distributor's rights for any reason, Distributor agrees to assist Company or any person or corporation designated by Company to obtain its own Health Regulatory Approvals.

3. Training, Promotional Materials and Inventory

3.1 Within ninety (90) days of the date of this Agreement, or such later date as the Company may hereafter specify, the Distributor shall cause its employee(s) (including, but not limited to, its Sales Associates) charged with responsibility for promotion and solicitation of sales of the Products to attend a training program at the Company's designated training facility at the Company's expense; provided, however, that all travel expenses incurred in connection therewith shall be the sole responsibility of the Distributor or the Sales Associates, as determined by the Distributor. The Distributor agrees that no employee shall perform services in connection with this Agreement unless and until such employee has developed requisite understanding about product and its application.

3.2 Upon completion of such training, the Company may provide the Distributor or its employee such promotional material as the Company may deem necessary for successful promotion and sale of the Products, including, such demonstration inventory as the Company deems appropriate. All such promotional materials shall remain the property of the Company until distributed by the Distributor to purchasers or potential purchasers of the Products. In addition, all such promotional material and items shall remain the Company's property. All promotional material and items (including, but not limited to instrumentation and demonstration inventory), so long as the same is the property of the Company pursuant to the foregoing, shall be preserved by the Distributor in good condition and shall be destroyed by the Distributor on demand and, in any event, upon termination of this Agreement.

3.3 Notwithstanding anything to the contrary herein, the risk of loss for all property related to the subject matter of this agreement, including but not limited to inventory, samples, or instrumentation, which is, at any time, in the possession or control of Distributor, whether owned and/or delivered to distributor by company or by a third party, shall be borne by Distributor, who shall be solely responsible for any such loss. In the event that distributor fails to deliver such property to company on demand, Company may use any and all available remedies to recover such property or the value thereof.

4. Obligations of Company

(i) In order to assist Distributor in the promotion and sale of the Products, the Company will, in its sole discretion, provide the following [illegible] assistance from time to time:

(a) Advertising, sales promotion aids, displays, catalogues, literature and convention assistance; excluding samples;

(b) New Product information and promotional activities;

(c) Assistance in training Distributor's personnel in the use of the Products.

Marketing literature and related items provided under this Clause shall be provided at Distributor's expense unless otherwise determined by Company.

(ii) Company agrees to indemnify and hold Distributor harmless from liability to third parties resulting from infringement of any patents, trademarks or trade names resulting from the sale of Products, or arising on account of warranty claims, product liability matters or any claimed defect or failure to perform of the Products and from the negligence of Company; provided Distributor promptly delivers to Company any notices, letters or papers served upon it in any proceeding or related matter covered by this indemnity. Distributor will give reasonable assistance and Company will have the sole control over defense and settlement. However Company will not be liable for any settlement reached by Distributor without express consent of the company in writing.

5. Sales & Inventory Forecasts; Sales Objectives

5.1 The Company has established sales objectives both in quantity and value term for Distributor's performance on an annual basis (splitted quarterly) as per EXHIBIT "C" based on a number of factors, prioritized and weighted by the Company. These factors include unit sales growth, Revenue sales growth, market share growth, comparison to overall performance by the Company, Product market expansion or contraction and other factors. The Company may adjust sales objectives at any time upon thirty (30) days notice to Distributor and if Distributor fails to meet ninety percent (90%) of its total quarterly sales objectives for 1st year (consolidated for all products) in value terms, the company shall be at liberty to terminate this agreement, impose extra conditions as it deems fit or appoint another Distributor or dealer for the same territory or take any other reasonable action to correct the situation without granting any compensation or remitting any kind of loss of profits to the Distributor.

5.2 Distributor will furnish on a monthly basis a rolling inventory forecast to the Company for subsequent 3 months in order to ensure smooth deliveries of the products.

5.3 Distributor will furnish data on monthly secondary deployment with batch number to the Company.

5.4 Distributor represent and warrants that, if the minimum order quantity referred in Exhibit "C" is not purchased by the distributor, then in the last month i.e 12th Month from the signing of this Agreement, the Distributor shall compulsorily purchase the balance quantity at the same prices by paying 100% advance payment irrespective of payment terms mentioned in clause 7.4 herein below.

6. Reporting

6.1 Distributor shall notify Company immediately within two days of

(i) all adverse comments or complaints by Distributor's customers regarding the Product, including comments regarding the Product's quality, stability, contamination, potency, condition, packaging, or any other attributes or defects, and

(ii) all adverse events and adverse reactions that may be attributable to a customer's use of the Product, whether or not Distributor can confirm that the event is actually associated with the Product, and whether or not Distributor can confirm that the event was due to improper dosing or other negligence on the part of the physician or patient. Distributor shall provide Company with information regarding the reporting requirements in the Territory within two days of such events or adverse reactions.

(iii) the non-compliance and of any corrective action taken

6.2 In the event of an actual or alleged malfunction or defect of a Product, Distributor or its representatives or Distributors shall not make any statement to any media, press, person or authority (unless required under legal process of the law of the land) as to the cause, effect, explanation, assurance or otherwise prior to receiving Company's written analysis of such malfunction or defect, and shall thereafter make no statements contrary to or inconsistent with the results of such analysis.

6.3 In the event to any recalls, safety alerts, advisory notices, or other remedial actions with respect to the Product, Distributor will use its best efforts to support and fully cooperate with Company to comply with applicable laws and regulations and will notify its customers and, at Company's request, retrieve any requested Product.

6.4 Company will replace & take back products, provided the product is replaced is received in original along with following supporting documents.

a) Incidence Reporting Form (IRF) / Product Feedback Form (PBF)

b) Application/Sales team confirmation letter along with confirmation from regarding hazard device return form.

c) Proof of Quality issues along with tested samples

The complaint product should be sent in sterile kits only provided by Company.

6.5 Company shall not accept any claim or objection arising from any claim or complaint which has not been reported to the Company in time.

6.6 Following are the contact persons for the purpose of routine business:

Company	**Meril Life Sciences Pvt. Ltd**
Contact Person	Mr. Chhagan Donode
Contact No.	+919930151764
Email ID	Chhagan.donode@merillife.com

Distributor	Lifemed SRL
Contact Person	Vlas Ion
Contact No.	+37360807745
Email ID	vlas.ion@lifemed.md

7. Pricing and Payment Term:

7.1 The products will be purchased by Distributor as per the pricing schedule attached in EXHIBIT "A". The pricing shall be CIF - Chisinau, Republic of Moldova. The sales billing by the Company to Distributor shall be made in EURO terms only and any fluctuation in currency exchange rate shall be borne by the distributor. The Bank charges incurred in India shall be borne the Company and any bank charges incurred in the country of Distributor shall be borne by the Distributor. The Distributor shall ensure that all banking and other laws of country of Distributor are complied by the Distributor. The dispatches of product from India and collection of payment in India is regulated by the Laws of Reserve Bank of India and Foreign Exchange Management Act and Distributor will allow and extend reasonable time to the Company to comply with such law and act.

7.2 The pricing can be changed by the company at its sole discretion by giving 30 days notice to the Distributor.

7.3 The distributor is required to sell each product at the Company recommended market price only. However the distributor may determine the final selling price to the market within rational business limits. Any discount offered by Distributor to the Customer on the sale of the product will be borne by the Distributor.

7.4 The Distributor will make payment within 45 days from the date of invoice for all purchases of products referred in Exhibit "A" made from the Company. It will be solely company's prerogative to decide if the payment terms have to be changed after a sales performance and payment history of 12 months from date of signing the contract.

7.5 In no case except as referred in the clause 15.2, the product sold by the Company to Distributor shall be taken back by the Company. The Distributor needs to have Inventory management in such a way where there is no expiry arises to the products and in case, it comes, it shall be borne by the Distributor. Company in no case shall be responsible and shall not indemnify to Distributor for any expiry arises for the Products already sold to the Distributor.

8. Samples

8.1 The Company will make available to Distributor a limited quantity of sample Products at no cost to Distributor. Distributor may purchase a limited quantity of additional samples, if available, at prices determined by the Company. Such samples may be used solely for demonstration and display purposes and may not be sold to Customers or otherwise disposed of by Distributor without the Company's prior written approval.

9. Confidential Information

9.1 Distributor acknowledges that, in connection with this Agreement and the performance of Distributor's obligations hereunder, Distributor will be acquiring and making use of certain confidential information of the Company or its third party licensors and supplies which includes, but is not limited to, management reports, financial statements, internal memoranda, reports, patient information and other materials or records of a confidential and proprietary nature ("Confidential Information"). In order to protect the Confidential Information, Distributor will not use such Confidential Information except in connection with the performance of its duties pursuant to this Agreement, or disclose such Confidential Information to any third party, unless the Company consents in writing to such use or disclosure. In the event Distributor receives a request or demand from a third party for the disclosure of Confidential Information, Distributor will promptly (within three (3) business days after receipt of such request or demand) provide written notice to the Company of such request or demand, including a copy of any such request or demand.

9.2 The foregoing restrictions will not apply to any information from [illegible] time it becomes public knowledge other than as a result of Distributor's breach of the provisions of Clause 9.1.

10. Trademarks, Service Marks and other Intellectual Property

10.1 Distributor may use Company's trade names, trademarks and service marks that are designated by Company for each Product (the "Company Intellectual Property") on a non-exclusive basis in the Territory, only for the duration of this Agreement and solely in connection with selling, marketing and distributing the Product in accordance with this Agreement. Permission to use such names and marks will automatically elapse upon termination of this contract (regardless of the reason for the termination), further use only being allowed for the performance of business as described herein. Distributor shall not register trademarks, trade names, internet domains and other symbols of Company (or symbols or names which are similar to those of Company) in its own name, neither inside nor outside the Territory. The Distributor shall at all times recognize the exclusive ownership and right of the Company in and to all Company Intellectual Property used or acquired by the Company in connection with the Products. Distributor shall, upon Company's request, cooperate with Company in any action necessary or desirable to register with the appropriate governmental agencies in the name of Company, any Company trademark used or proposed to be used hereunder, and to protect any Company trademark proposed to be used. Distributor shall not at any time do or permit any act to be done which may in any way impair the rights of Company in the Company Intellectual Property or the value of the Company Intellectual Property.

10.2 In order to comply with Company's quality control standards, Distributor shall:

(i) use the Company Intellectual Property in compliance with all relevant laws and regulations;

(ii) accord Company the right to inspect during normal business hours, without prior advance notice, Distributor's facilities used in connection with efforts to store or sell the Product in order to confirm that Distributor's use of such Company Intellectual Property is in compliance with this provision; and

(iii) not modify any of the Company Intellectual Property in any way and not use any of the Company Intellectual Property on or in connection with any goods or services other than the Product.

10.3 Distributor will not modify, alter or make any changes to the finished product or packaging supplied to the distributor by the Company for commercial sale, promotional products, demo units and or marketing material.

10.4 Any inventions made, developed, conceived, or reduced to practice by Distributor with reference to the Product (including any associated delivery systems), and any intellectual property relating thereto, shall be owned solely by

Company. Distributor hereby assigns and transfers to Company all right, title, and interest in and to such inventions and related intellectual property and agrees to take all further acts reasonably required to evidence such assignment and transfer to Company at Company's expense. Company hereby agrees to grant to Distributor a reasonable non-exclusive, royalty-free, nontransferable, non-sublicenseable license to such inventions made by Distributor for uses other than in the Product and associated delivery systems.

10.5 In no event Company will be responsible or liable for any Intellectual Property or Patent infringement arising out of the regulatory approval, launch or marketing of the said product in the country of import for sale. Company shall be held harmless against any damages and costs incurred as a result of any claim of infringement of Intellectual Property or Patent arising out of the Distributor's actions. It shall be the sole liability of the Distributor to defend Company in the event of any Intellectual Property or Patent infringement proceedings, in case Company is designated as a Contributory infringer.

10.6 In the event that Distributor shall become aware of any claim of infringement of Intellectual Property or Patent, Distributor will promptly within three days, notify Meril in writing and give Meril all necessary information to enable Meril to provide assistance for the defense of any such claim and its settlement, which will however be without prejudice to the disclaimer as hereinabove.

10.7 Distributor shall promptly within three days, notify Company in writing of any patent or copyright infringement or unauthorized use of Company trade secrets or trademarks which comes to the knowledge of the Distributor within the Territory in which Distributor is operating or at any other place. Company shall have the exclusive right in its sole discretion to institute any proceedings against such third party in its name and on its behalf. Distributor shall cooperate fully with Company in any legal action taken by Company against such third parties, provided that Company shall bear, all expenses of such action and all damages, settlement amount. Award or any other compensation which may be awarded or agreed upon in settlement of such action shall accrue to Company.

11. Non-Solicitation

11.1 For a period of twenty-four (24) months following termination of this Agreement for any reason whatsoever, Distributor will not, without the Prior written consent of the Company, either directly or indirectly, on its own behalf, or on behalf of any person, firm, corporation or other business or legal entity of any type, solicit, assist or in any way encourage any employee, contractor, Customer or consulting physician to terminate his or her relationship with or to the company, nor will Distributor solicit the services of any former employee, contractor or consulting physician of the Company whose service has been terminated for less than three (3) months from the date of termination of this

Agreement.

12. Other Representations and Warranties of Distributor

12.1 Distributor represents and warrants that no agreements, contracts, restrictive covenants, including covenants. Not to compete, written or oral, prohibit Distributor, or any owners, principals, employees or contractors of Distributor, from working for the Company as Distributor pursuant to the terms of this Agreement.

12.2 Distributor represents and warrants that neither Distributor nor any owners, principals, employees or contractors of Distributor, has been and during the term of this Agreement will be sanctioned within the meaning laws of the land in force from time to time.

12.3 Distributor represents and warrants that neither Distributor nor any owners, principals, employees or contractors of Distributor has had, and during the term of this Agreement will have, a complaint filed against him/her by any enforcement agency, which complaint alleges either felony criminal acts of a violent nature or any crime relating to the practice of medicine.

12.4 Distributor will extend co-operation to all the personnel employed or deputed by the Company for dealing with Distributor in any capacity whatsoever.

12.5 Distributor represents and warrants that Distributor will have in operation at all times during the term of this Agreement all licenses, permits and authorizations from all federal, state and local authorities necessary for the performance of the Services under this Agreement.

12.6 Distributor represents and warrants that, during the term of this Agreement, neither Distributor nor any owner, principal, manager, employee or contractor will engage, directly or indirectly, in any activity which materially conflicts with his/her faithful performance of the services, duties, covenants, commitments and obligations undertaken and to be performed pursuant to this Agreement.

12.7 Distributor agrees that all employees and contractors will be employed or engaged pursuant to a written agreement with Distributor, which agreement will require that such individual comply with all of the material terms and conditions of this Agreement including, but without limiting to the provision that such individual will at all times comply with all federal, state and local laws and regulations and in accordance with all the Company rules, procedures and that such individual will comply with and agree to be bound by the non-solicitation provisions of Clause 11 above. Distributor will indemnify the Company against any actions taken by an employee or contractor that either (i) violates a federal, state and local law or regulations; (ii) violates a company

rule, policy or procedure, or (iii) causes Distributor to breach any material term of this Agreement and causes harm (financially or by reputation) to the Company, a Customer or a patient served by a Customer.

12.8 The Distributor shall conduct all of its business in its own name and shall be solely responsible for the acts and expenses of its Sales Associates, employees, Sub-Distributors and affiliates. Nothing in this Agreement shall be construed to appoint the Distributor as a partner, employee or agent of the Company, nor shall either party have any authority to bind the other in any respect, it being intended that each shall remain an independent contractor responsible only for its own actions. The Distributor agrees that it shall not, directly or indirectly, represent to any person that it possesses authority to obligate the Company in any manner. Without limiting the generality of the foregoing, the Distributor further agrees that it shall not, without the Company's written permission, enlarge or limit orders, make representations or guarantees concerning the Products or make any credit allowances for the Products.

13. Term and Termination:

13.1 This Agreement shall be effective for a period of twelve (12) months beginning with the Effective Date and unless terminated earlier as follows:

a) By mutual agreement in writing of the Company and the Distributor;

b) By either party upon written notice to the other, by registered or certified mail, postage prepaid, at the address set forth below,

c) In the event that the either has dissolved its business, has filed against a petition in bankruptcy (which is not dismissed within thirty (30) days after it is filed), or has made an assignment for the benefit of its creditors;

d) By either party, upon ten (10) days' written notice to the other, in the event of the other party committing a material breach of this Agreement and failing to cure such breach within the said ten (10) days period ; or

e) By the Company, upon written notice to the Distributor, in the event of any change in the ownership or control of the Distributor, whether by reason of sale, assignment, death, creditors' proceedings or otherwise.

13.2 The Company may further terminate this Agreement, effective immediately upon written notice to Distributor, if Distributor:

a) Is charged with any felony, or is charged with any other criminal offense that is likely to affect the Distributor's business or the goodwill associated with

the Products;

b) Fails to comply with any law or government regulation;

c) Discloses or makes any unauthorized use of Confidential Information;

d) Fails to comply with the non-solicitation provisions of Clause 11 of this agreement;

e) Fails to meet established sales objectives for two (2) consecutive quarters;

f) Violates the law/s of the land in force from time to time;

g) Is found selling damaged or lost items to Customers;

h) Fails to provide Customer services in a way that is expected from Distributor.

i) Failure to pay the outstanding amount as per terms of payment ;

j) Is debarred, excluded or suspended from participation in any federal or state health care program; or

k) Becomes insolvent, or files or has filed against it a petition in bankruptcy, or has a receiver appointed, or executes an assignment for the benefit of creditors.

l) Failure of the Company to exercise its right to terminate this Agreement upon the occurrence of any of the events set forth above will not constitute a waiver of the Company's right to terminate this Agreement upon the occurrence of future events.

13.3 The termination of the Agreement by either party shall not entitle the Distributor to any termination or severance compensation or to any payment in respect to any goodwill established by the Distributor during the term of this Agreement or render the Company liable for damages on account of the loss of prospective profits or on account of any expenditure, investment or obligation incurred or made by the Distributor.

13.4 Upon any expiration or termination of this Agreement, Distributor will:

a) not directly or indirectly at any time or in any manner identify itself as a current or former Distributor of the Company or as otherwise associated with the Company;

b) cease use of and promptly within seven days, return to the Company all Confidential Information then in its possession or control or in the possession or control of any employee or contractor;

c) promptly within seven days return to the Company all samples of Products and promotional materials related to the Products or the Company.

The confidentiality and non-solicitation covenants contained in Clause 9.1 and clause 11 respectively will remain in full force and effect subsequent to and notwithstanding the expiration or termination of this Agreement. In addition, Distributor expressly agrees and acknowledges that it will continue to indemnify the Company in respect to all matters as to which indemnification by Distributor is covenanted herein notwithstanding such expiration or termination.

13.5 The Distributor's obligation to Company following expiration or termination of this Agreement will be to pay the outstanding payment for the purchase of Products by Distributor within the Territory in accordance with the Company's Policies in force at respective time periods.

13.6 In the event that this Agreement is terminated or not renewed by either party for any reason whatsoever, Distributor will make its best efforts to assure a smooth transition, will promptly return all property belonging to the Company, will return to the Company, all documents and all material stored in computer form, that relate in any way to the business of Company, will provide the Company with a list of all scheduled surgeries and will introduce Company's representative to all of Distributor's customers in the Territory. Neither party to this Agreement will disparage the other.

14. Change of Control of Company

14.1 For purposes of this Agreement, Change of Control means

I. any public report or notice is filled with any authority or any public announcement is made, that discloses that any person has become the beneficial owner, directly or indirectly, of 50 percent or more of the outstanding voting stock of Company;

II. any person purchases securities pursuant to an offer for cash or exchange of securities to acquire any voting stock of Company (or any securities convertible into voting stock of Company) and, immediately after consummation of that purchase, that person is the beneficial owner, directly or indirectly, of 50 percent or more of the outstanding voting stock of the

Company;

III. the consummation of

a) a merger, stock exchange plan, consolidation or reorganization of Company with or into any other entity if as a result of such merger, stock exchange plan, consolidation or reorganization, less than 50 percent of the combined voting power of the then-outstanding securities of such other person immediately after such merger, consolidation or reorganization are held in the aggregate by the holders of voting stock of the Company immediately prior to such merger, stock exchange plan, consolidation or reorganization;

b) any sale, lease, exchange or other transfer of all or substantially all the assets of Company and its consolidated subsidiaries to any other person if as a result of such sale, lease, exchange or other transfer, less than 50 percent of the combined voting power of the then-outstanding securities of such other person immediately after such sale, lease, exchange or other transfer are held in the aggregate by the holders of voting stock of the Company immediately prior to such sale, lease, exchange or other transfer; or

c) a transaction immediately after the consummation of which any person would be the beneficial owner or any successor rule or regulation promulgated under the Exchange Act), directly or indirectly, of more than 50 percent of the outstanding voting stock of Company; or

d) the dissolution of the Company is approved in accordance with the laws of the jurisdiction of formation of the Company.

14.2 In the event of change of control in the management or ownership structure of the company, this Distributorship agreement will continue and the company is authorized to assign, transfer, exchange for stock or cash, or in any other matter deal with this agreement as a part of overall assets, goodwill, rights, entitlements or otherwise and the Distributor will remain bound by such transfer, assignment, exchange or otherwise handing over of this agreement to a third party or entity till the validity of this contract.

14.3 In the event of a change of control of the Company, whether or not the agency relationship continues, the Distributor will continue to be bound by the confidentiality provisions and restrictive covenant provisions of sections 9.1 and 11 of this Agreement.

14.4 Any change of control in the management or ownership structure of the distributor will be promptly informed to the Company. The distribution

agreement will continue only if the Company gives a written prior consent for such continuance.

15. Warranty

15.1 As to all components of the Product manufactured by Company, Company warrants that, at the time of shipment, the Product supplied by Company hereunder :

(i) shall meet the Product specifications agreed to in writing by the parties,

(ii) shall be manufactured in accordance with cGMP as referred by Indian Drug and Cosmetic Act and ISO 13485 & 9001 guidelines provided,

However, that Company shall not be liable for any of the foregoing with respect to any product labeling or package inserts to be provided or used by Distributor, or any translation thereof, or for any noncompliance with the foregoing due to the handling or packaging of the Product by Distributor.

15.2 Under no circumstances shall the warranties set forth in Clause 15.1 apply to any Product which has been used with unapproved components or to any Product which has been customized or modified, damaged, reused, or misused. In the event that the warranties set forth in Clause 15.1 are breached and Company is responsible for such breach, Company will replace the defective product at no cost to Distributor. The provisions of the foregoing warranties are in lieu of any other warranty, whether express or implied, written or oral (including any warranty of merchantability or fitness for a particular purpose). Company's liability arising out of the manufacture, sale or supply of the products under this Agreement or the use or disposition of the products by Distributor or its customer, whether based upon warranty, contract, tort or otherwise, shall not exceed the actual purchase price paid by Distributor for the product. In no event shall Company be liable to Distributor or any other person or entity for special, incidental or consequential damages (including, but not limited to, loss of profits, loss of data or loss of use damages) arising out of the manufacture, sale or supply of the product even if company has been advised of the possibility of such damages or losses. Nothing in this Section is intended to be construed as relating to any claims asserted by either of the parties hereto against the other party claiming breach of any provision of this Agreement.

16. Assignment

16.1 Distributor will not assign, encumber, sub-license, transfer or otherwise deal with any of its rights or obligations under this Agreement without prior written consent of Meril.

16.2 Company can assign, encumber, sub-license, transfer or otherwise deal with any of its rights or obligations under this Agreement without prior written consent of Distributor.

17. Miscellaneous

17.1 This Agreement represents the entire agreement of the parties and there are no other oral or written understandings or agreements between the Company and Distributor relating to the subject matter of this Agreement except for documents or agreements expressly referred to as incorporated herein. This Agreement shall not be modified except by a written agreement signed by the parties. All references herein to the masculine, neuter or singular will be construed to include the masculine, feminine, neuter or plural, wherever applicable.

17.2 Neither this Agreement, nor any part of the privileges and obligations of Distributor hereunder may be directly or indirectly transferred, sold, conveyed, encumbered, Subdivided or otherwise assigned without the prior written consent of the Company, which may be granted or withheld in the Company's sole discretion. Any unauthorized transfer will constitute a breach hereof and conveys no rights to or interests in this Agreement. Subject to the foregoing, this Agreement is binding upon the parties hereto and their respective assigns and successors in interest.

17.3 It is understood and agreed that this Agreement does not create a franchise or employment relationship, that the parties are independent contractors. Distributor will not make any express or implied agreements, guaranties or representations, or incur any debt in the name of or on behalf of the Company nor will the Company be obligated by or have any liability for any agreements or representations made by Distributor that are not expressly authorized hereunder.

17.4 Each term and provision hereof will be severable if held to be invalid, contrary to or in conflict with any applicable law or regulation, and all other terms and provisions will remain in full force and effect. The parties will not be deemed to have waived any right under this Agreement by virtue of any custom or practice of the parties, any delay or omission in exercising rights, or any waiver, delay, forbearance or omission by the Company with respect to other Distributors.
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17.5 This Agreement shall be governed by and construed in accordance with the laws of India and all matter pertaining to this agreement or the matters arising as consequence of this agreement will be subject to the jurisdiction of courts in Gujarat, India.

17.6 The Distributor acknowledges that any breach of this Agreement by it may give

rise to irreparable injury to the Company which may not be adequately compensated by damages. Accordingly, in the event of a breach or a threatened breach of this Agreement by the Distributor, the Company shall have, in addition to any remedies it may have at law, the right to an injunction or other equitable relief to prevent the violation of its rights hereunder, including but not limited to the right to obtain restraining orders and injunctions from a court of competent jurisdiction with respect to enforcement of: (a) Distributor's confidentiality obligations under Clause 9; and (b) Distributor's non-solicitation obligations under Clause 11. Distributor agrees that the Company may have such injunctive relief without bond, but upon due notice and Distributor's sole remedy in the event of the entry of such injunctive relief will be the dissolution of such injunctive relief, if warranted (all claims for damages by reason of the wrongful issuance of any such injunction being expressly waived hereby).

17.7 All notices under this Agreement will be deemed delivered at the time delivered by hand, one(1) business day after transmission by facsimile, telecopy or other electronic system (with a confirmation copy sent by commercial overnight courier), or one (1) business day after being placed in the hands of a commercial overnight courier for next business day delivery.

17.8 All notices under this Agreement will be deemed delivered addressed to following contact persons at following addresses:

Distributor:
Lifemed SRL
Contact person: Mr. Ion Vlas
Address: 30 Todor Strisca St., Chisinau MD2048,
Republic of Moldova
Mobile: +37360807745
Off: +37369225934
Email id: vlas.ion@lifemed.md

Company:

Meril Life Sciences Pvt. Ltd.,
Survey No.135/139, Bilakhia House,
Muktanand Marg, Chala, Vapi
Gujarat, India
Phone +91 260 2408 000
Fax : +91 260 2408 025
Email id: compliance@merillife.com

Addresses written above by the Parties in this Agreement has been accepted as legal address. In case of change of address to the circumstance that the parties shall notify each other in writing within one week. Otherwise, the

notifications/notices to be made to the address written in the contract shall be deemed valid.

17.9 Distributor shall have no right to enter into any contracts or commitments in the name of, or on behalf of, Company, or to bind Company in any respect - whatsoever. In addition, Distributor shall not obligate or purport to obligate Company by issuing or making any affirmations, representations, warranties or guaranties with respect to the Product to any third party.

17.10 Distributor agrees that any publicity or advertising which shall be released by it in which Company is identified in connection with the Products shall be in accordance with the terms of this Agreement and with any information or data which Company has furnished in connection with this Agreement. Copies of all such publicity and advertising shall be forwarded in advance to Company for approval, which shall not be unreasonably withheld.

17.11 Company may from time to time maintain an office at one or more locations in or near the Territory. Personnel associated with such office or offices shall be authorized to and may, from time to time, act on behalf of Company and shall be entitled to exercise all of the rights of Company under this Agreement, and Distributor shall at all times cooperate with such personnel with respect to all such matters.

18. Force Majeure

18.1 No liability for damages. Neither Company nor Distributor shall be liable in damages, or shall be subject to termination of this Agreement by the other party, for any delay or default in performing any obligation hereunder if that delay or default is due to any cause beyond the reasonable control and without fault or negligence of that party; provided that, in order to excuse its delay or default hereunder, a party shall notify the other of the occurrence or the cause, specifying the nature and particulars thereof and the expected duration thereof; and provided, further, that within fifteen (15) calendar days after the termination of such occurrence or cause, such party shall give notice to the other party specifying the date of termination thereof. All obligations of both parties shall return to being in full force and effect upon the termination of such occurrence or cause (including without limitation any payments which became due and payable hereunder prior to the termination of such occurrence or cause).

18.2 For the purposes of this Section, a "cause beyond the reasonable control" of a party shall include, but not limited to the generality of the phrase, [illegible] act of any government or other authority or statutory undertaking, industrial dispute, fire, explosion, accident, power failure, flood, riot or war (declared or undeclared).