

FORM-26

(See Rules 73 and 83)

Certificate of renewal of Licence to manufacture for sale of drugs other than those specified in Schedule X.

1. Certified that Licence No. 04/SC/P of 2012 granted on the Form-28 to **M/s B.L. Lifesciences Pvt. Ltd.**, for the manufacture of the following categories of drugs other than those specified in Schedule C, C (1) & X to the Drugs and Cosmetics Rules, 1945, at the premises situated at **28-D, Sector-31, Ecotech-I, Greater Noida, Gautam Budh Nagar (U.P.)** have been renewed from 05.10.2017 to 04.10.2022.

2. **Name of approved (competent) Technical Staff:**

Manufacturing Chemist : (i) Mr. Sanjay Kachru

Analytical Chemist : (i) Mr. Hemant Singh
(ii) M/s Shree Balaji Test Lab (Pvt.) Ltd., C-181, Naraina Industrial Area, Phase-I, New Delhi

Note: Approved laboratories are allowed only for tests and analysis requiring sophisticated instrumentation techniques, biological tests, microbiological tests (excluding sterility test).

3. **Names of drugs : (each item to be separately specified):**

Medical Devices (As per List Enclosed)

4. The licensee shall abide by the provisions of Drugs Price (Control Order) 2013.

Dated: 24/4/2018, 2018


Dr. S. ESWARA REDDY
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi-110002


(A.K. Jain)
Drug Licensing and Controlling Authority
Uttar Pradesh
Drugs Licensing and Controlling Authority
Uttar Pradesh (India)

OFFICE OF THE COMMISSIONER, FOOD SAFETY & DRUG ADMINISTRATION, U.P.,
Sector-C, Aliganj, Lucknow

List of Items M/s B.L. Lifesciences Pvt. Ltd., 28-D, Sector-31, Ecotech-I, Greater Noida,
 Gautam Budh Nagar (U.P.)

sterile only

A. Catheter

S. No	Product	Brand Name	Specification		Shelf Life
			Tubing Size	Component	
1	Thoracic Drainage Catheter	SurgX	Tubing Length: 45 cm Catheter size: 8 Fr to 36 Fr	Connector	3 Years
2	Hemodialysis Catheter	DiaX	Catheter Length: 13/16 cm/20 cm Catheter size: 6.5 Fr to 12 Fr	Dilator, Guidewire, Needle, Scalpel, Syringe	3 Years
3	Central Venous catheter	VenX	Catheter Length: 4/6/8/10/13/16/20 cm Catheter size: 4 Fr to 9 Fr	Dilator, Guidewire, Needle, Syringe/Introducer Syringe, Y Needle	3 Years
4	Angiographic catheter	AngiX	Catheter Length: 65/80/90/100/110/120 cm Catheter size: 4 Fr to 6 Fr	Catheter	3 Years

B. Angio Kit

sterile only

S. No	Product	Brand Name	Specification		Shelf Life
			Tubing Size	Component	
5	Angio Kit PTCA Kit Cath Lab Kit Accessories of Angio Kit	Angix	Tubing size- 0.11, 0.16" inch Tubing Length: 60-80" inch	Configuration: Manifolds 2 gang Kit Manifolds 3 gang Kit Manifolds-2/3/4/5 Core Right on/off Control syringe- 10/12/20 ml Hemostasis Y-Click Y/Large Bore Insertion Tool/ Blunt Needle -20G, 10 cm Inflation Device-30 ml High Pressure tubing- 25/50/120 cm Torque Device High pressure Stopcock/ Manifold	3 Years

V. G. SOMANI
 Dr. V. G. SOMANI
 Joint Drugs Controller (India)
 Directorate General of Health Services
 FDA Bhawan, Kirti Road, New Delhi-110002

(A. K. Jain)
 Drugs Licensing and Controlling Authority
 Uttar Pradesh (India)

6	Introducer Needle	AngiX	Length: 7/4 cm Size: 18G, 20G, 21G	---	3 Years
7	Guidewire	AngiX	Length: 45/60/75/70/ 150/260 cm Size: 0.018", 0.021", 0.025", 0.032", 0.035", 0.038"	---	3 Years
8	Introducer Sheath	AngiX	Length: 7/10/11cm Size: 4 Fr to 9 Fr	Sheath, Guidewire, Dilator, Needle, Syringe, Scalpel	3 Years

V. G.
Dr. V. G. SOMANI
Joint Drugs Controller (India)
Director General of Health Services
FDA Bhawan, Connaught Place, New Delhi-110092

A. K. Jain
(A. K. Jain)
Drugs Licensing and Controlling Authority
Uttar Pradesh (India)

OFFICE OF THE COMMISSIONER, FOOD SAFETY & DRUG ADMINISTRATION, U.P.,

Sector-C, Aliganj, Lucknow

Encl. No. Drug/6028/ 1011

Lucknow: Dated, 24/4/2018

A. Disposable Perfusion Set

S. No.	Product	Brand Name	Specification		Shelf Life
			Tubing Size	Component	
1	Heart Lung Pack	PerfX	Sizes of Tubing: 1/4" , 3/8" , 1/2" , 3/16" , 1/8" inches Length: as per customer requirement 1 ft to 12 ft	Arterial filter- Adult/ Pediatric/ Semi Adult Hemoconcentrator kit - Adult/ Pediatric Suction Tubing HLP Connector- Straight/Y, With/Without Luer Lock Tourniquet Set- Adult/ Pediatric Mister Blower – with/without handle Purge Line Gas filter BT Filter Set Heat Exchanger – with/without aluminium spiral	3 Years

B. Fluid Delivery System

S. No.	Product	Brand Name	Specification		Shelf Life
			Tubing Size	Component	
2	Pressure monitoring Kit/ Disposable transducer kits	IpeX	Size: 0.16" inch, 0.11" inch, 0.14" inch Length: 04 inch – 80 inch	Disposable Pressure Transducer, Flush Device, Tubing, Luer Locks, Caps, Stopcock, Sampling Device, Syringe 6ml red, Syringe cover silicon	3 Years
3	Pressure Monitoring Line	IpeX	Length: 04-80 inch Size: 0.11 inch	Tubing, Luer locks, caps	3 Years
4	IV Set	IpeX	Size: 0.16" inch Length: 60 inch	Drip chamber, Luer Locks, Tubing, Roller Clamp	3 Years
5	Measure Volume Set	IpeX	Size: 0.16" inch Length: 15/58/60 inch	Drip chamber, Luer Locks, Tubing, Roller Clamp	3 Years
6	Flow regulator Line	IpeX	Size: 0.16" inch Length: 4/12 inch	Flow regulator, Tubing, Roller Clamp, Luer Locks	3 Years
7	Extension line	IpeX	Size: 0.16" inch Length: 4-80 inch	Tubing, Roller Clamp, Luer Locks	3 Years

(A. K. Jain) 24/4/18
Drug Licensing and Controlling Authority
Uttar Pradesh (INDIA)

CERTIFICATE

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH awards this **qualityaustria** certificate to the following organisation:

This **qualityaustria** certificate confirms the application and further development of an effective

BL Lifesciences Pvt. Ltd

A-245, Okhla Industrial Area, Phase-I,
New Delhi-110020, India

Site: 28-D, Sector 31, Ecotech-I, Greater Noida,
Gautam Budh Nagar (U.P.) 201306, India

QUALITY MANAGEMENT SYSTEM

complying with the requirements of standard

EN ISO 13485:2016

Medical devices - Quality management systems -
Requirements for regulatory purposes

Design & Development, Production, Storage,
Marketing & Distribution of Sterile Medical Disposable
Devices for Cardiovascular, Critical care, Anaesthesia,
Infusion/Perfusion Therapy & General procedures

Registration No.: 00277/0

Date of initial issue: 19 December 2017

Valid until: 18 December 2023

The validity of the **qualityaustria** certificate will be
maintained by annual surveillance audits and one
renewal audit after three years.

Vienna, 17 December 2020

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH,
AT-1010 Vienna, Zelinkagasse 10/3



Konrad Scheiber
General Manager



Ing. Andreas Aichinger, MSc
Specialist representative

Quality Austria - Trainings,
Zertifizierungs und
Begutachtungs GmbH is
accredited according to
the Austrian Accreditation
Act by the BMVFW
(Federal Ministry of
Science, Research and
Economy).

Quality Austria is
accredited as an
organisation for
environmental verification
by the BMLFUW (Federal
Ministry of Agriculture,
Forestry, Environment and
Water Management).

Quality Austria is
authorized by the VDA
(Association of the
Automotive Industry).

For accreditation
registration details please
refer to the applicable
decisions or recognition
documents.

Quality Austria is the
Austrian member of IQNet
(International Certification
Network).

Dok. Nr. FO_24_028

11868dcf-b37b-4357-
8439-68d731db7dfe

The current validity of the certificate is documented exclusively on the Internet under
<http://www.qualityaustria.com/en/cert> EAC: 19.2