HIMEDIA®

HiMedia Laboratories Pvt. Ltd.

Digitally signed by Iurcu Nicolae
Date: 2019.11.14 12:02:41 EET
Reason: MoldSign Signature
Location: Moldova

EC DECLARATION OF CONFORMITY

1. We declare that our products, specified under following categories as listed below, comply to and are manufactured according to the requirements of the International Standards as specified in the In Vitro Diagnostic Medical Devices Directive 98/79/EC.

   - Dehydrated Culture Media and Supplements
   - Culture Media Bases
   - Antimicrobial Susceptibility Systems
   - Bacteriological Differential Aids
   - Cell Culture Media
   - Lymphocyte and Granulocyte Separation Media
   - Latex Agglutination Test Kits
   - Epidemiological Screening Kit

2. Company or its authorized representative :

   Name : Mr. Federico Pontigia, (Company – Neomed S.R.L.)
   Address : Via G.DI Vittorio, 2-A, 20017 Mazzo Di Rho, MILANO, ITALY
   Phone : 00-39-02-93900652/93902434
   Fax : 00-39-02-93900968
   Email : neomed@neomed.it
   shall fulfill the obligations imposed by in vitro medical device directives as applicable.

3. Company undertakes to keep upto 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 and risk in relation to the product.

4. Company undertakes to notify immediately any malfunction/ deterioration of the performance of the product to the appropriate authority and shall recall such products already placed in the market.

For HiMedia Laboratories Private Limited, India

Dated : 15th November, 2011

CEO, Dr. G.M. Warke

Digitally signed by Iurcu Nicolae
Date: 2020.11.24 11:30:15 EET
Reason: MoldSign Signature
Location: Moldova

Registered Office :
23, Vadhani Industrial Estate,LBS Marg,
Mumbai - 400 086, India.
Tel. : (022) 4017 9797 / 2500 1607
Fax : (022) 2500 2286

Commercial Office
A-516, Swastik Disha Business Park,
Via Vadhani Indl. Est., LBS Marg,
Mumbai - 400 086, India

Tel: 00-91-22-6147 1919
Fax: 6147 1920, 2500 5764
Email : info@himedialabs.com
Web : www.himedialabs.com

CERTIFICATE

Quality Austria Central Asia Private Limited
(A Division of Peacock Global Company)
Awards this Certificate to

This Certificate confirms the application
and further development of an effective

WHO GMP Compliance Verification

Complying with the requirement of

WHO GMP Guidelines

HIMEDIA®

HiMedia Laboratories Private Limited

Unit I : B/4-6, MIDC, Palkhed, Dindori, Nashik-422 202, Maharashtra, India.
Unit II : W-239(B), MIDC Phase II, Shivaji Udyog Nagar, Dombivli, District Thane – 421 204, Maharashtra, India.
Unit III : K-45 Addl Ambernath MIDC Anand Nagar East, District Thane – 421506, Maharashtra, India.

Report No.:2020/QACA/002
Issue Date: 07/01/2020
Expiry Date: 06/01/2023

Unit I : Manufacture & supply of biosciences products for applications in microbiology (includes dehydrated culture media, culture media bases, antimicrobial susceptibility systems & bacteriological differentiation aids), animal cell culture, plant tissue culture and molecular biology.

Unit II : Manufacture and supply of sterile ready prepared media.

Unit III : Manufacture and supply of sterile ready prepared media.

The validity of this Certificate will be maintained via annual surveillance audits and one renewal audit after three years.

qualityaustria central asia
Succeed with Quality

India: 07 January 2020

Quality Austria Certification Private Limited (A division of Peacock Global company)

Sanjeev Tiwari
(GM- Strategic Business C&T)

The Product and Systems Liability rests with the manufacturer and under no circumstances Quality Asustria Central Asia Shall be Held Responsible

The current validity of the certificate is documented exclusively on the Internet under www.qualityaustriacentralasia.com

भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDARDS
गुणता प्रबंध पद्धति प्रमाणन लाइसेंस
LICENCE FOR THE QUALITY MANAGEMENT SYSTEMS CERTIFICATION

अनुज्ञप्ति सं. क्यूएम/एल-7000485.7
Licence No. QM/L- 7000485.7

ब्यूरो, भारतीय मानक ब्यूरो अधिनियम, 2016 (2016 का 11) द्वारा प्रदत्त शक्तियों के नाते निम्नलिखित को पुनः प्रमाणन देता है:
By virtue of the power conferred on it by, the Bureau of Indian Standards Act, 2016 (11 of 2016), the Bureau hereby recertified to:-

मे. हायमीडिया लबोरेटरीज़ प्रा. लि.
ए- 516, स्वास्तिक दिशा बिजनेस पार्क,
एल.बी.एस मार्ग, घाटकोपर (प.)
मुंबई - 400 086*

M/s Himedia Laboratories Pvt. Ltd.,
A-516, Swastik Disha Business Park,
L.B. S. Marg, Ghatkopar (W)
*Mumbai – 400 086**

(जिसे इसमें इसके पश्चात इसे अनुज्ञप्तिधारी कहा गया है) इस अनुसूची में वर्णित विशेष तौर पर उत्पाद एवं/ या सेवाओं की प्रक्रियाओं के संबंध में गुणता प्रबंध पद्धति प्रमाणन के अनुज्ञप्तिधारकों की ब्यूरो की सूची में इस अनुज्ञप्ति के अनुसार इसी संख्याधारक को अधिकार एवं अनुज्ञप्ति सूचीबद्ध किया जाए । IS/ISO 9001:2015 के अनुसार गुणता प्रबंध प्रणाली के अधीन उक्त दिए गए पते (पतों) पर केवल अनुज्ञप्तिधारक द्वारा ऐसे उत्पाद एवं/ या सेवाओं या प्रक्रियाओं को निर्मित किया/ उपलब्ध कराया/ चलाया जायेगा।

(hereinafter called the Licensee) the right and licence to be listed in the Bureau's list(s) of Licensees of **Quality** Management Systems Certification in respect of the products and/or services or processes particularly described in the schedule hereto, bearing the same number as this licence. Such products and/or services or processes shall be manufactured/provided/carried out by the Licensee at only the address (es) given above, and under the **Quality** Management Systems in accordance with **IS/ISO 9001:2015**

अनुज्ञप्ति उक्त अधिनियम एवं उनके अधीन नियमों तथा विनियमों के संबंधित उपबंधों की शर्तें पर पुनः प्रमाणन किया गया है तथा उक्त संदर्भित अनुज्ञप्तियों को इसके तहत शासित किया जाता है, तथा अनुज्ञप्तिधारक उक्त नियमों एवं विनियमों का पालन किए जाने के लिए ब्यूरो के प्रति प्रतिज्ञाबद्ध है ।

The licence is recertified subject to the relevant provisions of the above Act and the rules and regulations made thereunder governing the licences referred to above, and the Licensee hereby covenants with the Bureau duly to observe with the said Rules and Regulations.

यह अनुज्ञप्ति 22 जून 2018 से 31 मार्च 2021 तक विधिमान्य रहेगा तथा विनियमों में यथा निहित पुनः प्रमाणन दिया जा सकेगा।

This licence shall be valid from **22 June 2018** to **31 March 2021** and may be recertified as prescribed in Regulations.

सन दो हजार अठारह के अगस्त माह के दूसरे दिन हस्ताक्षरित/ मुहरांकित।
Signed, Sealed and dated this **Second day of August Two Thousand Eighteen**

महिम जैन, उपमहानिदेशक (प.)
Mahim Jain, DDGW
भारतीय मानक ब्यूरो के लिए
For BUREAU OF INDIAN STANDARDS

Last Certification Expiry – N.A **Certification Audit Date: 05-09 June 2018** **Recertification Due Date: 31 Mar 2021**

भारतीय मानक ब्यूरो IS / ISO 9001 BUREAU OF INDIAN STANDARDS QMS

प्रारूप III [विनियम 7 (1) D (d) देखें]
Form III [see Regulation 7 (1) D (d)]
MSC-F6.4-12

15th November, 2011

AGREEMENT & REPRESENTATION

With this letter of agreement and representation, HiMedia Laboratories Private Limited, India, appoints an authorized representative in the EC to represent the company. The details of the authorized representative are given below:

Name : Mr. Federico Pontigia, (Company-Neomed S.R.L)
Address : Via G. DI Vittorio, 2-A, 20017 Mazzo Di Rho, MILANO, ITALY
Phone : 00-39-02-93900652/93902434
Fax : 00-39-02-93900968
Email : neomed@neomed.it

HiMedia Laboratories Private Limited, India shall, through this authorized representative, fulfill all the obligations imposed by the Directive 98/79/EC of the European parliament and of the Council of the European Union on *In Vitro* Diagnostic Medical devices and ensure that the products of the company meet all provisions of the directives as applicable from time to time.

HiMedia Laboratories Private Limited, India will be responsible for all legal and insurance matters pertaining to our products.

For HiMedia Laboratories Private Limited, India

CEO, Dr. G.M. Warke

I agree to represent HiMedia Laboratories Private Limited, India and be appointed as their EU Representative as per the tenets above.

EU Representative
Name: Mr. Federico Pontigia

NEOMED
s.r.l.
Via G. DI VITTORIO,
20017 MAZZO DI RHO (MI)
Tel. 02/939.00.652-939.01.463-939.02.434
Fax 02/939.00.968
C.F./P. I. 09580650159
C.C.I.A.A. 1304819 - TRIB. MILANO 291273