

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



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

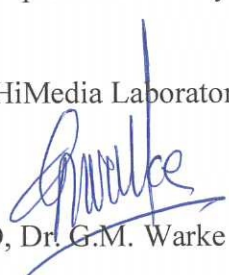
Fax : 00-39-02-93900968

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


CEO, Dr. G.M. Warke

Dated : 15th November, 2011



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 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 Ambarnath MIDC Anand Nagar East,
District Thane – 421506, Maharashtra, India.

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.

Report No.:2020/QACA/002

Issue Date: 07/01/2020

Expiry Date: 06/01/2023



**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
Austria
Central Asia
Shall be Held
Responsible

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



मानक: पद्यप्रदर्शक:

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सर्मा III (विनियम 7 (1) D (d) देखें)
orm III (see Regulation 7 (1) D (d))

MSC-F6.4-12

भारतीय मानक ब्यूरो BUREAU OF INDIAN STANDARDS

गुणता प्रबंध पद्धति प्रमाणन लाइसेंस

LICENCE FOR THE QUALITY MANAGEMENT SYSTEMS CERTIFICATION

अनुज्ञति सं. क्यूएम/एल-7000485.7

Licence No. QM/L- 7000485.7

द्व्यूरो, भारतीय मानक ब्यूरो अधिनियम, 2016 (2016 का 11) द्वारा प्रदत्त शक्तियों के माते 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. हयमीडिया लबोरेटरीज 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 पश्चात् इसे अनुज्ञतिधारी कहा गया है) इस अनुज्ञति में वर्णित विशेष तौर पर उत्पाद एवं/ या सेवाओं की प्रक्रियाओं के संबंध में गुणता प्रबंध पद्धति प्रमाणन के अनुज्ञतिधारकों की द्व्यूरो की सूची में इस अनुज्ञति के अनुसार इसी संख्याधारक को अधिकार एवं अनुज्ञति स्वीकृत किया जाए। IS/ISO 9001:2015 के अनुसार गुणता प्रबंध प्रणाली के अधीन अर्पित दिए गए पते (पत्तों) पर केवल अनुज्ञतिधारक 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

अनुज्ञति उक्त अधिनियम एवं उनके अधीन नियमों तथा विनियमों के संबंधित उपबंधों की शर्त पर पुनः प्रमाणन किया गया है तथा उक्त संदर्भित अनुज्ञतियों को इसके तहत शक्ति किया जाता है, तथा अनुज्ञतिधारक उक्त नियमों एवं विनियमों का पालन किए जाने के लिए द्व्यूरो 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 अनुज्ञति 22 जून 2018 से 31 मार्च 2021 तक विधिमन्य 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, उपप्रमाणनदेशक (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



15th November, 2011**AGREEMENT & REPRESENTATION**

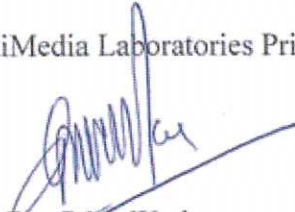
With this letter of agreement and representation, HiMedia Laboratories Private Limited, India, appoints an authorized representative in the EC to represent the company. The details of the authorized representative are given below:

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

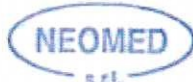


CEO, Dr. G.M. Warke

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



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