

Date: 01st December 2017**STATEMENT**

We, **HiMedia Laboratories Pvt. Ltd.**, having a registered office at A-516, Swastik Disha Business Park, Via Vadhani Industrial Estate, L.B.S. Marg, Mumbai – 400 086, INDIA, assign **SRL SANMEDICO** having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova , as authorized representative in correspondence with the conditions of directive 98/79/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

For HIMEDIA LABORATORIES PVT. LTD.,



Mr. V.M. WARKE.



DIRECTOR – SALES & MARKETING

DECLARATION OF CONFORMITY

1) Manufacturer (Name, department): **HiMedia Laboratories Pvt. Ltd.**
Address: 23 Vadhani Industrial Estate, LBS Marg, Mumbai - 86, MS, India
 and

2) European authorized representative: **CEpartner4U BV,**
Address: ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS;
 (on product labels printed as:
 CEpartner4U , ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS. www.cepartner4u.eu)

3) Product(s) (groupnames /.):

| Group | Group name | NL registration no. | No. |
|-------|---|---------------------|-----|
| DCM&S | Dehydrated Culture Media & Supplements | NL-CA002-2013-26442 | 1 |
| RPM | Ready Prepared Media Subgroups: Ready Prepared Plates, Ready Prepared Liquid & Solid Medium, Ready Prepared Slants, Ready Prepared Dual Media, HiDip Slides, HiSafe Blood Culturing System, Transport Medium w/ swabs, Viral Transport Medium w/ swabs, L.J. Medium Slants & Kits, Biochemical Kits for Mycobacteria, UTI Diagnostic Kits, Biochemical Identification Kits | NL-CA002-2013-26448 | 2 |
| ESK | Epidemiological Screening Kit: Subgroups: Hi Aureus Confirmation Kits | NL-CA002-2012-24117 | 3 |
| ASS | Antimicrobial Susceptibility Systems Subgroups: Sensitivity Discs-Single & Multi Discs MIC Strips: HiComb Strips & Ezy MIC Strips | NL-CA002-2013-26444 | 4 |
| BDA | Bacteriological Differentiation Aids Subgroups: Readymade Stains, Indicators & Reagents in liquid, Differentiation Discs & Strips, HiDtect Rapid Identification Discs | NL-CA002-2013-26445 | 5 |
| CCM | Cell Culture Media Subgroups: Karyotyping Media, Stem Cell Differentiation Media & Supplements, Stem Cell Freezing Medium, Stem Cell Differentiation Kits ,Viral Transport Medium, Balanced Salt Solutions, Antibiotic solutions, Animal Cell Culture Medium Liquid | NL-CA002-2013-26446 | 6 |
| MBP | Molecular Biology Products Subgroups: DNA & RNA Isolation Kits, Latex Agglutination Kits, Haematology Kits, Density gradient Separation Medium, PCR Kits | NL-CA002-2013-26447 | 7 |

type and model numbers: see appendix


4) The product(s) described above is in conformity with:

| Title | Document No. |
|---|--------------|
| In vitro Diagnostic Medical Devices Directive | 98/79/EC |

5) Additional information (Conformity procedure, Notified Body, CE certificate, Registration nr., etc.):
 Conformity assessment procedure for CE marking: *In vitro* Diagnostic Medical Device Directive, Annex III

Mumbai, India; 2018-30-10

(Place & date of issue (yyyy-mm-dd))


 Dr. G.M. Warke , Managing Director
 (name; function and signature of manufacturer)



qualityaustria
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CERTIFICATE

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



HiMedia Laboratories Private Limited

Unit-1 B-4-5-6 / MIDC, Paikhed, Dindori,
Nashik - 422 202 Maharashtra, India

Registered Office : 23, Vadhani Industrial Estate,
LBS Marg, Ghatkopar (West) Maharashtra, India

Design and Development, Manufacturing and Supply of Biosciences Products for application in Microbiology (including Dehydrated culture Media, Antimicrobial Susceptibility Systems, Culture Media Bases and Bacteriological Differentiation Aids), Animal Tissue Culture, Plant Tissue Culture and Molecular Biology

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

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

QUALITY MANAGEMENT SYSTEM

complying with the requirements of standard

EN ISO 13485:2016

Medical devices - Quality management systems - Requirements for regulatory purposes

Registration No.: 00275/0

Date of initial issue: 21 November 2017

Valid until: 31 March 2022

Vienna, 08 April 2019

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

Konrad Scheiber
Konrad Scheiber
General Manager

Ing. Andreas Aichinger
Ing. Andreas Aichinger, MSc
Specialist representative



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



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CERTIFICATE

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



HiMedia Laboratories Pvt. Ltd.
23, Vadhani Industrial Estate L. B. S. Marg,
Ghatkoper (W), Mumbai - 400086, Maharashtra,
India

Unit-1: B-4-5-6, MIDC, Palkhed, Dindori,
Nashik - 422 022, Maharashtra, India

Design and Development, Manufacturing and Supply of Biosciences Products for application in Microbiology (including Dehydrated culture Media, Antimicrobial Susceptibility Systems, Culture Media Bases and Bacteriological Differentiation Aids), Animal Tissue Culture, Plant Tissue Culture, Molecular Biology

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

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

QUALITY MANAGEMENT SYSTEM
complying with the requirements of standard
ISO 9001:2015

Registration No. 17285/0

Date of initial issue: 29 December 2015

Valid until: 21 November 2020

Vienna, 22 November 2017

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

Konrad Scheiber

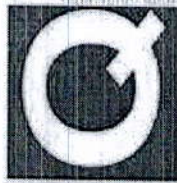
Konrad Scheiber
General Manager

Dr. Mag. Anni Koubek

Dr. Mag. Anni Koubek
Specialist representative



The current validity of the certificate is documented exclusively on the Internet under
<http://www.qualityaustria.com/en/cert>
EAC: 23



CERTIFICATE



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



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.

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.

The Product and Systems Liability rests with the manufacturer and under no circumstances

Quality Austria Central Asia Shall be Held Responsible

This Certificate confirms the application and further development of an effective

WHO GMP Compliance Verification

Complying with the requirement of

WHO GMP Guidelines

Report No.:2020/QACA/002

Issue Date: 07/01/2020

Expiry Date: 06/01/2023



**qualityaustria
central asia**
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India: 07 January 2020

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

Sanjeev Tiwari
(GM- Strategic Business C&T)



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