

Date: 01<sup>st</sup> 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 Pvt. Ltd.**  
23, Vadhani Industrial Estate L.B.S Marg,  
Ghatkopar (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*  
General Manager

*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





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# CERTIFICATE

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



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

Unit-1, B-4-5-6, MIDC, Palkhed, Dindori,  
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The validity of the **qualityaustria** certificate will be maintained by annual surveillance audits and one renewal audit after three years

## QUALITY MANAGEMENT SYSTEM

complying with the requirements of standard  
**EN ISO 13485:2012**  
Medical devices - Quality management systems - Requirements for regulatory purposes

Registration No.: 00275/0

Date of initial issue: 21 November 2017

Valid until: 31 March 2019

Vienna, 22 November 2017

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

*Konrad Schelber*  
Konrad Schelber  
General Manager

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



37710-01-01-2017

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



# CERTIFICATE

This Certificate confirms the application and further development of an effective

**WHO GMP Compliance System**  
Complying with the requirement of  
**WHO GMP Guidelines**

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

**HiMedia Laboratories Pvt. Ltd.**

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 : D-61 MIDC, Phase-II, Near Shani Mandir, Dombivli, District Thane – 421204, 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 Media  
**Unit II :** Manufacture and supply of Sterile Ready Prepared Media  
**Unit III :** Manufacture and supply of Sterile Ready Prepared Media

Report No.: QACA/WHO/069  
Issue Date: 21/12/2016  
Expiry Date: 20/12/2019

 **qualityaustria**  
**central asia**  
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India: 20 Dec 2016  
Quality Austria Central Asia Private Limited (A division of Peacock Global company)

  
Ansh Kumar  
Country Head

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

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

The entire validity of this certificate is documented exclusively on the internet under [www.qualityaustriacentralasia.com](http://www.qualityaustriacentralasia.com)