

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, HiDect 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)



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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



**HiMedia Laboratories
Private Limited**

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

Registered Office : 23, Vadhani Industrial Estate,
LBS Marg, Ghalkopar (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

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/certif> EAC: 19 2



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CERTIFICATE

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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, Palghed, Dindori,
Nashik - 422 022, Maharashtra, India

Design and Development, Manufacturing and Supply
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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



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<http://www.qualityaustria.com/en/cert> EAC: 23