CEpartner4U

Certificate number: 2019-IVD/247

Certificate of CE-Registration

This is to certify that, in accordance with the *In Vitro* Diagnostic Medical Device Directive 98/79/EC, **CEpartner4U BV** agrees to perform all duties and responsibilities as the Authorized Representative for

Himedia Laboratories PVT. LTD

23 Vadhani Industrial Estate,
LBS Marg, Mumbai - 86, MS,
India

as stipulated and demanded by the aforementioned Directive. The Dutch Competent Authorities have accepted the manufacturer's medical device registrations by CEpartner4U as listed on the product list attached to the manufacturer's Declaration of Conformity:

IVD devices were registered under number:

Group 1 : Dehydrated Culture Media & Supplements	**Registration No: NL-CA002-26442**
Group 2 : Ready Prepared Media	**Registration No: NL-CA002-26448**
Group 3 : Epidemiological Screening Kit	**Registration No: NL-CA002-24117**
Group 4 : Antimicrobial Susceptibility Systems	**Registration No: NL-CA002-26444**
Group 5 : Bacteriological Differentiation Aids	**Registration No: NL-CA002-26445**
Group 6 : Cell Culture Media	**Registration No: NL-CA002-26446**
Group 7 : Molecular Biology Products	**Registration No: NL-CA002-26447**

see appendix

with Dutch Competent Authorities as a consequently these IVD devices were entered in EUDAMED by Dutch Competent Authorities

The manufacturer has provided CEpartner4U with all necessary documentation, together with an appropriate Declaration of Conformity that the IVD medical devices fulfil the essential requirements of Directive 98/79/EC.

Issue date: 2019-07-03

Olga Teirlinck
Consultant CEpartner4U BV

CEpartner4U
Esdoornlaan13
3951 DB Maarn NL
tel: +31 (0)343 442 524
www.cepartner4u.nl

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Date: 2021.06.01 11:07:28 EEST
Reason: MoldSign Signature
Location: Moldova

REPUBLICA MOLDOVA, mun. CHIŞINĂU S.R.L. "SANMEDICO" IDNO 1003602015154 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

DECLARATION OF CONFORMITY
MICROBIOLOGY PRODUCTS

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, HiComb™ MIC Strip, Modified & Ezy MIC Strips, HiMIC™ Plate Kit	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

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; 2020-11-10

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

Dr. G.M.Warke, Managing Director

(name; function and signature of manufacturer)

REPUBLICA MOLDOVA, mun. CHIŞINĂU S.R.L. "SANMEDICO" IDNO 1003602006 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

qualityaustria
Succeed with Quality

CERTIFICATE

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

This **quality**austria 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, 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 **quality**austria certificate will be maintained by annual surveillance audits and one renewal audit after three years.

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: 31 March 2022

qualityaustria

Vienna, 08 April 2019

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

Konrad Scheiber
General Manager

Dr. Mag. Anni Koubek
Specialist representative

Quality Austria - Trainings Zertifizierungs und Begutachtungs GmbH is accredited according to the Austrian Accreditation Act by the BMWFW (Federal Ministry of Science, Research and Economy).

Quality Austria is accredited as an organisation for environmental validation by the BMLFUW (Federal Ministry of Agriculture, Forestry, Environment and Water Management).

Quality Austria is authorized by the VDA (Association of the Automotive Industry).

For accreditation registration details please refer to the applicable decisions or recognition documents.

Quality Austria is the Austrian member of IQNet (International Certification Network).

Doc.-Nr. FO_ZA_028

70e43900-3928-4bc1-bf7f-6f130e3e0969

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

S.R.L. "SANMEDICO" IDNO 1

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CERTIFICATE

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

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, 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 **quality**austria certificate will be maintained by annual surveillance audits and one renewal audit after three years.

This **quality**austria 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

qualityaustria
PARTNER OF IQNet

Vienna, 08 April 2019

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

Konrad Scheiber
General Manager

Ing. Andreas Aichinger, MSc
Specialist representative

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH is accredited according to the Austrian Accreditation Act by the BMWFW (Federal Ministry of Science, Research and Economy).

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Quality Austria is authorized by the VDA (Association of the Automotive Industry).

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Quality Austria is the Austrian member of IQNet (International Certification Network).

Doc. Nr. 60_24_058

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