

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:

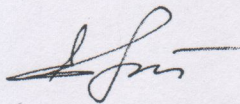
Group 1 : Dehydrated Culture Media & Supplements	Registration No: NL-CA002-26442
Group 2 : Ready Prepared Media	Registration No: NL-CA002-26448
Group 3 : Epidemiological Screening Kit	Registration No: NL-CA002-24117
Group 4 : Antimicrobial Susceptibility Systems	Registration No: NL-CA002-26444
Group 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

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



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, HiDect 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

Dr. G.M. Warke, Managing Director

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

(name; function and signature of manufacturer)





qualityaustria
Succeed with Quality

CERTIFICATE

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

HIMEDIA

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

Registered Office : 23, Vadhami 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
ISO 9001:2015

Registration No.: 17285/0

Date of initial issue: 29 December 2015

Valid until: 31 March 2022

Vienna, 08 April 2019

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

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: 19.2



Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH is an Austrian company registered in the Austrian Trade Register, Act by the BUNDESGESAMTANZEIGEN (Federal Ministry of Science, Research and Economy).
Quality Austria is accredited as an independent certification body for the ISO 9001 standard by the BAFUG (Federal Agency of Approval, Accreditation and Certification) in the field of Quality Management.
Quality Austria is authorized by the VCA (Austrian Chamber of Auditors) for the certification of ISO 9001 and ISO 14001.
For registration, registration status, please refer to the respective documents or documents.

Doc. No. FA-2019-008
7043300-3323-4601-
071-8135348/0529



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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

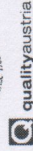
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AT-1010 Vienna, Zelinkagasse 10/3

Scheiber
Konrad Scheiber
General Manager

Andreas Aichinger
Ing. Andreas Aichinger, MSc
Specialist representative



Quality Austria is
accredited for the
regulatory purposes for
microbiological production
by the BAU-PLW (Federal
Bureau of Agriculture
and Forestry, Vienna,
Austria).

Quality Austria is
accredited by the VCA
Austrian Accreditation
Authority (Innsbruck, Austria).

For accreditation
requirements please contact
Quality Austria for
further information.

Quality Austria is the
Authorized Signatory of the
International Certification
Network.

Doc. No. QA-24-008
04/24/2019-2023-1374
31/03/22-03/25/2411



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