

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)





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

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

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Date of initial issue: 29 December 2015

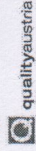
Valid until: 31 March 2022

Vienna, 08 April 2019

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

Scheiber
Konrad Scheiber
General Manager

Dr. Mag. Anni Koubek
Dr. Mag. Anni Koubek
Specialist representative



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704-43600-3323-4601-
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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

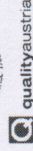
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Scheiber
Konrad Scheiber
General Manager

Stefel
Ing. Andreas Aichinger, MSc
Specialist representative



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