

## Declaration of Conformity Microbiology Products

Document ref.: DoC 2020 vs. 13

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## 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) <u>European authorized representative</u>: 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	NL-CA002-2013-26448	2
	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		
ESK	Epidemiological Screening Kit:	NL-CA002-2012-24117	3
	Subgroups: Hi Aureus Confirmation Kits		
ASS	Antimicrobial Susceptibility Systems	NL-CA002-2013-26444	4
	Subgroups: Sensitivity Discs-Single & Multi Discs		
	MIC Strips: HiComb Strips, HiComb™ MIC Strip, Modified &		
	Ezy MIC Strips, HiMIC™ Plate Kit		
BDA	Bacteriological Differentiation Aids	NL-CA002-2013-26445	5
	Subgroups: Readymade Stains, Indicators & Reagents in liquid, Differentiation Discs &		
	Strips, HiDtect Rapid Identification Discs		

type and model numbers: see appendix

The product(s) described above is in conformity with:

<u>Title</u>	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)

Declaration form: Standard ISO/IEC 17050-1:2010