

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; 2019-04-22

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

Dr. G.M.Warke, Managing Director

(name; function and signature of manufacturer)

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





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EC DECLARATION OF CONFORMITY

We hereby declare that the devices described below comply with those provisions which apply to them of the European Directive 98/79/EC on *in vitro* diagnostic medical devices, as set out in UK Statutory Instrument 2002 No. 618 "The Medical Device Regulations."

This declaration is valid for the IVD medical devices described below which are placed on the market by ourselves on or after the date hereof and which bear the CE mark. It is also valid for all the IVD medical devices described below which are manufactured by us and placed on the market on or after the date hereof by third parties with our consent and which bear the CE mark. All supporting documents relating to this declaration are retained at the manufacturer's premises.

Product code	Product description	IVD Directive classification	EDMS code
Various	MAST® ID identification test paper products - discs, rings and strips. Products for presumptive identification of biochemical reactions or detection of a specific reaction profiles in microbes.	Self certification Annex III excluding section 6	1402020100, 1402020200, 1402020400, 1402020800, 1402029000. (codes registered - 24/03/2003)

Standards applied: EN ISO 13485:2016, ISO 9001:2015, EN ISO 14971:2012, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 15223-1:2016, EN ISO 15223-2:2010.

Declaration made by Date: 30 January 2019

D N Hogben, Quality Assurance and Regulatory Affairs Manager – Mast Group Ltd.

Document valid till: 31 December 2021




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European In Vitro Diagnostic Medical Directive 98/79/EC, Annex III – General IVD
 EC DECLARATION OF CONFORMITY- Self-Certification (Annex III excluding section 6) – General IVD

Annex – list of MAST® ID identification test paper products

Serial No.	Device ID Number	Product Description	Pack Size	Brand Name	Intended purpose of the medical device type
1	D40C	Bacitracin Discs 0.04 units	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Group A streptococci.
2	D40	Bacitracin Discs 0.04 units	100 Discs	MASTDISCS® ID	For presumptive Identification of Group A streptococci.
3	D41C	Bacitracin Discs 0.1 Unit	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Group A streptococci.
4	D41	Bacitracin Discs 0.1 Unit	100 Discs	MASTDISCS® ID	For presumptive Identification of Group A streptococci.
5	D42C	Optochin Discs 5ug	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Strep. pneumoniae.
6	D42	Optochin Discs 5ug	100 Discs	MASTDISCS® ID	For presumptive Identification of Strep. pneumoniae.
7	D43C	X Factor Discs	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Haemophilus spp.
8	D43	X Factor Discs	100 Discs	MASTDISCS® ID	For presumptive Identification of Haemophilus spp.
9	D44C	V Factor Discs	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Haemophilus spp.
10	D44	V Factor Discs	100 Discs	MASTDISCS® ID	For presumptive Identification of Haemophilus spp.
11	D45C	X+V Factor Discs	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Haemophilus spp.
12	D45	X+V Factor Discs	100 Discs	MASTDISCS® ID	For presumptive Identification of Haemophilus spp.





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Serial No.	Device ID Number	Product Description	Pack Size	Brand Name	Intended purpose of the medical device type
13	D46C	Metronidazole Discs	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Gardnerella vaginalis.
14	D46	Metronidazole Discs 50ug	100 Discs	MASTDISCS® ID	For presumptive Identification of Gardnerella vaginalis.
15	D47C	Sulphathiazole Discs	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Gardnerella vaginalis.
16	D47	Sulphathiazole Discs 1ug	100 Discs	MASTDISCS® ID	For presumptive Identification of Gardnerella vaginalis.
17	D48	Lysostaphin Discs 20ug	50 Discs	MASTDISCS® ID	For presumptive Identification of Staphylococci/micrococci.
18	D49	ALA Discs 75ug	100 Discs	MASTDISCS® ID	For presumptive Identification of Haemophilus spp.
19	D51C	Nitrate Discs	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Nitrate Reductase in anaerobes.
20	D52C	Extended Spectrum β Lactamase Set	6 x 50 Discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
21	D55C	SPS Identification Discs	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Nitrate Reductase in P. anaerobius.
22	D55	SPS Discs 1000ug	100 Discs	MASTDISCS® ID	For presumptive Identification of P. anaerobius
23	D56C	ONPG Discs	5 x 50 Discs	MASTDISCS® ID	For the detection of β -galactosidase activity.
24	D56	ONPG Discs	100 Discs	MASTDISCS® ID	For the detection of β -galactosidase activity.
25	D57C	Oxidase Discs	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Nitrate Reductase in Pseudomonas spp.
26	D57	Oxidase Discs	100 Discs	MASTDISCS® ID	For presumptive Identification of Pseudomonas spp.
27	D59	Nitrocefin Discs (B)	50 Discs	MASTDISCS® ID	For presumptive Identification of Beta lactamase activity.
28	D62C	Cefotaxime 30 & Cefotaxime 30/Clavulanic Acid 10	6 x 50 Discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.





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Serial No.	Device ID Number	Product Description	Pack Size	Brand Name	Intended purpose of the medical device type
29	D63C	Cefepime 30 & Cefepime 30/Clavulanic Acid 10	6 x 50 Discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
30	D64C	Ceftazidime 30 & Ceftazidime 30/Clavulanic Acid 10	6 x 50 Discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
31	D66C	Cefpodoxime 10 & Cefpodoxime 10/Clavulanic Acid 1	6 x 50 Discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
32	D67C	Extended Spectrum β Lactamase Set (CPD10)	6 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
33	D68C	AmpC & ESB L Detection Set	4 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
34	D69C	AmpC Detection Set	3 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
35	D70C	Carbapenemase Detection Set	4 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
36	D71C	CAT ID - Carbapenemase Activity Test (CAT) discs	5 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
37	D72C	mastdiscs® combi AmpC, ES β L and Carbapenemase Detection Disc Set	6 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
38	D73C	Carba Plus. For the detection of carbapenemase and OXA-48 enzyme production in Enterobacteriaceae.	5 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
39	D74	mastdiscs® ID Indirect Carbapenemase Test (ICT)	25 Tests	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
40	STOX	Oxacillin Strips	50 Strips	MAST® ID	Oxacillin Strips for the detection of MRSA- Antibiotic Susceptibility Testing.
41	ETO/1	MAST® ID Intralactam Strips	25 strips	MAST® ID	A strip test for the rapid detection of β -lactamase.
42	ETO2	MAST® ID Intralactam Circles	10 circles	MAST® ID	A test for the detection of β -lactamase production. For use on multipoint inoculated plates.
43	ETO4	MAST® ID Oxidase Strips - for the performance of the oxidase reaction	25 strips	MAST® ID	A strip test for the rapid detection of cytochrome oxidase enzyme (Oxidase) in bacteria.
44	ETO6	MAST® ID Aesculin Strips - for the detection of aesculin hydrolysis	25 strips	MAST® ID	A strip test for the detection of aesculin hydrolysis.





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Serial No.	Device ID Number	Product Description	Pack Size	Brand Name	Intended purpose of the medical device type
45	ETO7	MAST® ID PYR Strips - for the detection of pyrrolidonyl amino peptidase activity	25 strips	MAST-ID	A rapid strip test for the detection of pyrrolidonyl amino peptidase activity in streptococci and enterococci.
46	MIID/XV	MAST® ID XV Mirror ring. MASTRING™ containing X+V factor tips	50 rings	ID-MASTRING	For the identification of haemophilus spp.
47	MID13	MASTRING containing Chloramphenicol (25ug), Erythromycin (5ug), Fusidic Acid (10ug), Oxacillin (5ug), Novobiocin (5ug), Penicillin G (1 unit), Streptomycin (10ug), Tetracycline (25ug)	50 rings	ID-MASTRING	For the identification of non-sporing anaerobes.
48	MID8	MASTRING containing Erythromycin (60ug), Rifampicin (15ug), Colistin Sulphate (10ug), Penicillin G 2 units, Kanamycin (1000ug), Vancomycin (5ug)	6 x 50 tests	ID-MASTRING	For the presumptive identification of Gram negative non-sporing anaerobes.
49	TEM30C	Temocillin Discs 30ug	5 x 50 Discs	MASTDISCS® ID	To aid presumptive Identification of OXA-48.





Diagnostic de laborator și dispozitive medicale de uz personal

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**Către grupul de lucru Achiziții Publice al
Agenției naționale pentru sănătate publică
Achiziție cu costuri mici nr. 21027068 din 14.08.2020**

Data: 14.08.2020

DECLARAȚIE

Prin prezenta, compania SRL Sanmedico, pentru pozițiile câștigătoare la procedura de achiziție cu costuri mici nr. 21027068 din 14.08.2020, garantează că:

1. Termenul de valabilitate, la livrare, indicat pe ambalaj de producător va fi nu mai mic de 80-90% din cel inițial;
2. În momentul livrării bunurilor se va prezenta certificatul de calitate și certificatul IVD (pentru pozițiile, care au acest certificat).

Cu respect,

Goreacii Vitalie

Administrator SRL



Sanmedico



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