



SRL SANMEDICO
A. Corobceanu Street 7A, apt. 9,
Chişinău MD-2012,
Moldova

Mast Group Ltd.
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www.mast-group.com

TO WHOM IT MAY CONCERN

LETTER OF AUTHORISATION

This letter is to confirm, SRL SANMEDICO of address A. Corobceanu Street 7A, apt. 9, Chişinău MD-2012, Moldova is authorised to register products, present proposals, offer quotations and accept orders and to participate in tenders as required for Mast Group Limited products.

The undersigned herewith states that the above is true and correct.

Yours faithfully,

A handwritten signature in black ink, appearing to read "Susan Thomson".

Susan Thomson

Bootle UK

December 9th 2021

International business Manager, on behalf of Mast Group

Digitally signed by Monastîrschii Viorica
Date: 2023.03.23 14:05:10 EET
Reason: MoldSign Signature
Location: Moldova







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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', and are placed on the European market by Mast Group UK through our appointed EC Authorised Representative Mast Diagnostica GmbH, Feldstrasse 20, 23858 Reinfeld, Germany.

This declaration is valid for the IVD medical devices described below on or after the date hereof, and which bear the CE mark. It is also valid for all IVD medical devices described below which are manufactured by Mast 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 14971:2019, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 15223-1:2016, EN ISO 15223-2:2010.

Declaration made by Date: 22 March 2022

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

Document valid till: 26th May 2025



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.



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	D55	SPS Discs 1000ug	100 Discs	MASTDISCS® ID	For presumptive Identification of P. anaerobius
22	D57C	Oxidase Discs	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Nitrate Reductase in Pseudomonas spp.
23	D57	Oxidase Discs	100 Discs	MASTDISCS® ID	For presumptive Identification of Pseudomonas spp.
24	D59	Nitrocefin Discs (B)	50 Discs	MASTDISCS® ID	For presumptive Identification of Beta lactamase activity.
25	D62C	Cefotaxime 30 & Cefotaxime 30/Clavulanic Acid 10	6 x 50 Discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
26	D63C	Cefepime 30 & Cefepime 30/Clavulanic Acid 10	6 x 50 Discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.in Enterobacteriales.
27	D64C	Ceftazidime 30 & Ceftazidime 30/Clavulanic Acid 10	6 x 50 Discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
28	D66C	Cefpodoxime 10 & Cefpodoxime 10/Clavulanic Acid 1	6 x 50 Discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.



Serial No.	Device ID	Product Description	Pack Size	Brand Name	Intended purpose of the medical device type
29	D67C	Extended Spectrum β Lactamase Set (CPD10)	6 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
30	D68C	AmpC & ESBL Detection Set	4 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
31	D69C	AmpC Detection Set	3 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
32	D70C	Carbapenemase Detection Set	4 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
33	D71C	CAT ID - Carbapenemase Activity Test (CAT) discs	5 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
34	D72C	MastDiscs® Combi AmpC, ESBL and Carbapenemase Detection Disc Set	6 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
35	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.
36	D74	MastDiscs® ID Indirect Carbapenemase Test (ICT)	25 Tests	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
37	D76C	MastDiscs® Combi ESBL Detection Set	50 Tests	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
38	STOX	Oxacillin Strips	50 Strips	MAST® ID	Oxacillin Strips for the detection of MRSA-Antibiotic Susceptibility Testing.
39	ETO/1	MAST® ID Intralactam Strips	25 strips	MAST® ID	A strip test for the rapid detection of β -lactamase.
40	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.
41	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.
42	MIID/XV	MAST® ID XV Mirror ring. MASTRING™ containing X+V factor tips	50 rings	ID-MASTRING	For the identification of haemophilus spp.
43	MID8	MASTRING containing Erythromycin (60ug), Rifampicin (15ug), Colistin Sulphate (10ug), Penicillin G 2 units, Kanamycin (1000ug), Vancomycin (5ug)	50 rings	ID-MASTRING	For the presumptive identification of Gram negative non-sporing anaerobes.



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Product code	Product description	IVD Directive classification	EDMS code
Various (DM---)	MAST® Dehydrated culture media – Powdered product formulations for use in microbial culture media.	Self certification Annex III excluding section 6	1401010100, 1401010200, 1403010100 (Codes registered - 24/03/2003) GMDN codes 30630, 30660

Standards applied: EN ISO 13485:2016, ISO 9001:2015, EN ISO 14971:2019, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 15223-1:2016, EN ISO 15223-2:2010.

Declaration made by Christine Winstanley

Date: 26 May 2022

Christine Winstanley, Quality Assurance and Regulatory Affairs Manager – Mast Group Ltd.

Document valid till: 26th May 2025



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

Product Names: Mast Dehydrated Culture Media

Serial No.	Device ID Number	Product Description	Pack Size	EDMS/GMDN code	Brand Name	Intended purpose of the medical device type
1	DM095D	Baird-Parker Medium	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
2	DM494D	Buffered Peptone Water	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
3	DM494E	Buffered Peptone Water	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
4	DM269D	Buffered Rappaport Vassiliadis Broth	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
5	DM253D	Burkholderia cepacia Medium	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
6	DM110A	C.L.E.D. Medium	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
7	DM110B	C.L.E.D. Medium	10x500ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
8	DM110D	C.L.E.D. Medium	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
9	DM111D	C.L.E.D. with Andrade's Indicator	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
10	DM111E	C.L.E.D. with Andrade's Indicator	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
11	DM119E	Cooked Meat Granules	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media



Serial No.	Device ID Number	Product Description	Pack Size	EMDS/GMDN code	Brand Name	Intended purpose of the medical device type
12	DM130D	D.C.A. (Hynes)	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
13	DM215B	D.S.T. Agar (Sulphonamide Antagonist Free)	10x 500ml	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
14	DM215D	D.S.T. Agar (Sulphonamide Antagonist Free)	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
15	DM132D	DNase Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
16	DM133D	Eosin Methylene Blue Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
17	DM136D	G.C. Agar Base	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
18	DM134D	Hektoen Enteric Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
19	DM134E	Hektoen Enteric Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
20	DM146D	Kimmig Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
21	DM137D	Kligler's Iron Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
22	DM138-1D	Kohn's No 1 Medium	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
23	DM258D	Legionella BCYE Agar Base	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
24	DM440D	M.S.R.V. (Salmonella) Medium	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
25	DM140D	MacConkey Agar (without salt)	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
26	DM140E	MacConkey Agar (without salt)	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media



Serial No.	Device ID Number	Product Description	Pack Size	EMDS/GMDN code	Brand Name	Intended purpose of the medical device type
27	DM141D	MacConkey Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
28	DM141E	MacConkey Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
29	DM142D	MacConkey Agar No.2	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
30	DM143D	MacConkey Agar No.3	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
31	DM143E	MacConkey Agar No.3	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
32	DM150D	MacConkey Broth	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
33	DM160D	Mannitol Salt Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
34	DM170B	Mueller Hinton Agar	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
35	DM170D	Mueller Hinton Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
36	DM170E	Mueller Hinton Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
37	DM171D	Mueller Hinton Broth	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
38	DM171N	Mueller Hinton Broth	20Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
39	DM195D	Plate Count Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
40	DM251D	Preston Blood Free Campylobacter Agar Base	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
41	DM205D	S.S. Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media



Serial No.	Device ID Number	Product Description	Pack Size	EMDS/GMDN Code	Brand Name	Intended purpose of the medical device type
42	DM205E	S.S. Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
43	DM211D	Simmons Citrate Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
44	DM491D	Sorbitol MacConkey Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
45	DM218D	T.C.B.S. Cholera Medium	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
46	D401D	T.C.B.S. Cholera Medium	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
47	DM219S	Tetrathionate Broth	460g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
48	DM221D	Thioglycollate Broth USP	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
49	DM224D	Triple Sugar Iron Agar (TSI)	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
50	DM228D	Urea Agar Base	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
51	DM228S	Urea Solution (40% v/v)	10 x10ml	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
52	DM480D	Violet Red Bile (Lactose) Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
53	DM235D	Wilkins Chalgren Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
54	DM230D	X.L.D. Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
55	DM230E	X.L.D. Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
56	DM496D	Yeast Extract Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media



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Serial No.	Device ID Number	Product Description	Pack Size	EMDS/GMDN Code	Brand Name	Intended purpose of the medical device type
57	DM252D	Yersinia Agar Base	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media



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Product code	Product description	IVD Directive classification	EDMS code/ GMDN code
Various (M-----)	MAST® ASSURE Salmonella Antisera – for serological identification and epidemiological typing of Salmonella bacteria.	Self certification Annex III excluding section 6	EDMS code - 1501000000 (code registered - 24/03/2003) GMDN code - 39521

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 C Winstanley Date: 26th May 2022

C Winstanley, Quality Assurance and Regulatory Affairs Manager – Mast Group Ltd.

Document valid till: 26th May 2025



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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
Product Names: MAST® ASSURE Salmonella Antisera

Serial No.	Product code	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
1	M10308	2ml	MAST® ASSURE Salmonella O - POLY O Factor O2, O4, O7, O8, O9, O46, O3, 10, O1,3,19	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
2	M10309	2ml	MAST® ASSURE Salmonella O - POLY O1 Factor O11, O13, O6, 14, O16, O18, O21, O35	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
3	M14294	2ml	MAST® ASSURE Salmonella O - POLY O A-G	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
4	M14300	2ml	MAST® ASSURE Salmonella O - POLY O A-S	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
5	M92537	2ml	MAST® ASSURE Salmonella O - Omnivalent (Kauffmann-White group A-067)	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
6	M14317	2ml	MAST® ASSURE Salmonella H - POLYVALENT PHASE 1&2 (a-z29)	Liquid stable polyvalent antiserum for the determination of H antigens for the serological identification of salmonellae by slide agglutination.
7	M10339	2ml	MAST® ASSURE Salmonella H - POLYVALENT PHASE 2 (H-1)	Liquid stable polyvalent antiserum for the determination of H antigens for the serological identification of salmonellae by slide agglutination.
8	M14324	2ml	MAST® ASSURE Salmonella H - RAPID DIAGNOSTIC 1 Factors b, d, E, r	Liquid stable polyvalent antiserum for the determination of H antigens for the serological identification of salmonellae by slide agglutination.
9	M14331	2ml	MAST® ASSURE Salmonella H - RAPID DIAGNOSTIC 2 Factors b, E, k, l	Liquid stable polyvalent antiserum for the determination of H antigens for the serological identification of salmonellae by slide agglutination.
10	M14348	2ml	MAST® ASSURE Salmonella H - RAPID DIAGNOSTIC 3 Factors d, E, G, k	Liquid stable polyvalent antiserum for the determination of H antigens for the serological identification of salmonellae by slide agglutination.



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Serial No.	Product code	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
11	M10310	2ml	MAST® ASSURE Salmonella O - Mono Factor O2	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
12	M10311	2ml	MAST® ASSURE Salmonella O - Mono Factor O4	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
13	M10312	2ml	MAST® ASSURE Salmonella O - Mono Factor O7	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
14	M10313	2ml	MAST® ASSURE Salmonella O - Mono Factor O8	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
15	M10314	2ml	MAST® ASSURE Salmonella O - Mono Factor O9	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
16	M10315	2ml	MAST® ASSURE Salmonella O - Mono Factor O9.46	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
17	M10316	2ml	MAST® ASSURE Salmonella O - Mono Factor O3,10	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
18	M10318	2ml	MAST® ASSURE Salmonella O - Mono Factor O1,3,19	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
19	M10319	2ml	MAST® ASSURE Salmonella O - Mono Factor O11	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
20	M10320	2ml	MAST® ASSURE Salmonella O - Mono Factor O13	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
21	M10321	2ml	MAST® ASSURE Salmonella O - Mono Factor O6,14	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
22	M10322	2ml	MAST® ASSURE Salmonella O - Mono Factor O16	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
23	M10323	2ml	MAST® ASSURE Salmonella O - Mono Factor O18	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
24	M10324	2ml	MAST® ASSURE Salmonella O - Mono Factor O21	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
25	M10325	2ml	MAST® ASSURE Salmonella O - Mono Factor O35	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
26	M10326	2ml	MAST® ASSURE Salmonella O - Mono Factor Vi	Liquid stable antiserum for the determination of Vi antigens for the serological identification of salmonellae by slide agglutination.



**Mast
Group**

Serial No.	Product code	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
27	M10327	2ml	MAST® ASSURE Salmonella H - Mono Factor a	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
28	M10328	2ml	MAST® ASSURE Salmonella H - Mono Factor b	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
29	M10329	2ml	MAST® ASSURE Salmonella H - Mono Factor c	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
30	M10330	2ml	MAST® ASSURE Salmonella H - Mono Factor d	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
31	M10331	2ml	MAST® ASSURE Salmonella H - Mono Factor e, h	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
32	M14335	2ml	MAST® ASSURE Salmonella H - Mono Factor E	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
33	M10332	2ml	MAST® ASSURE Salmonella H - Mono Factor G	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
34	M10333	2ml	MAST® ASSURE Salmonella H - Mono Factor i	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
35	M10334	2ml	MAST® ASSURE Salmonella H - Mono Factor k	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
36	M10336	2ml	MAST® ASSURE Salmonella H - Mono Factor r	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
37	M10344	2ml	MAST® ASSURE Salmonella H - Mono Factor 2	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
38	M10345	2ml	MAST® ASSURE Salmonella H - Mono Factor 5	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
39	M10346	2ml	MAST® ASSURE Salmonella H - Mono Factor 6	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
40	M10364	2ml	MAST® ASSURE Salmonella H - Mono Factor f	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
41	M10365	2ml	MAST® ASSURE Salmonella H - Mono Factor m	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
42	M10366	2ml	MAST® ASSURE Salmonella H - Mono Factor p	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.



**Mast
Group**

Serial No.	Product code	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
43	M10367	2ml	MAST® ASSURE Salmonella H - Mono Factor q	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
44	M10368	2ml	MAST® ASSURE Salmonella H - Mono Factor s	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
45	M10369	2ml	MAST® ASSURE Salmonella H - Mono Factor t	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
46	M10376	2ml	MAST® ASSURE Salmonella H - Mono Factor x	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
47	M10335	2ml	MAST® ASSURE Salmonella H - Mono Factor L	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
48	M10337	2ml	MAST® ASSURE Salmonella H - Mono Factor y	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
49	M10338	2ml	MAST® ASSURE Salmonella H - Mono Factor e,n	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
50	M10340	2ml	MAST® ASSURE Salmonella H - Mono Factor v	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
51	M10341	2ml	MAST® ASSURE Salmonella H - Mono Factor w	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
52	M10342	2ml	MAST® ASSURE Salmonella H - Mono Factor z13	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
53	M10343	2ml	MAST® ASSURE Salmonella H - Mono Factor z28	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
54	M10347	2ml	MAST® ASSURE Salmonella H - Mono Factor 7	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
55	M10348	2ml	MAST® ASSURE Salmonella H - Mono Factor z6	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
56	M10370	2ml	MAST® ASSURE Salmonella H - Mono Factor u	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
57	M10372	2ml	MAST® ASSURE Salmonella H - Mono Factor z23	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
58	M10373	2ml	MAST® ASSURE Salmonella H - Mono Factor z24	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.



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Serial No.	Product code	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
59	M10377	2ml	MAST® ASSURE Salmonella H - Mono Factor z15	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
60	M10374	2ml	MAST® ASSURE Salmonella H - Mono Factor z32	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
61	M10378	2ml	MAST® ASSURE Salmonella H - Mono Factor z	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
62	M10379	2ml	MAST® ASSURE Salmonella H - Mono Factor z4	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
63	M10380	2ml	MAST® ASSURE Salmonella H - Mono Factor z10	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
64	M10381	2ml	MAST® ASSURE Salmonella H - Mono Factor z29	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.



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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', and are placed on the European market by Mast Group UK through our appointed EC Authorised Representative Mast Diagnostica GmbH, Feldstrasse 20, 23858 Reinfeld, Germany.

This declaration is valid for the IVD medical devices described below on or after the date hereof, and which bear the CE mark. It is also valid for all IVD medical devices described below which are manufactured by Mast 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 DISCS® AST – paper antimicrobial susceptibility test (AST) disc products. Each disc contains an antimicrobial agent of stated content in conformance to recognised AST standards such as European Committee on Antimicrobial Susceptibility Testing - EUCAST or US Clinical and Laboratory Standards Institute - CLSI.	Self-certification Annex III excluding section 6	1402050200 (Code registered - 02/12/2002) GMDN code - 63834

Standards applied: EN ISO 13485:2016, ISO 9001:2015, EN ISO 14971:2019, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 15223-1:2016, EN ISO 15223-2:2010.

Declaration made by C Winstanley

Date: 18th May 2022

C Winstanley, Quality Assurance and Regulatory Affairs Manager – Mast Group Ltd.

Document valid till: 18th May 2025



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
 Product Names: Mast® Disc AST products

Annex – list of Mast® Disc AST products

Serial No.	Device ID Number	Product Description	Method of use	Pack Size	Brand Name	Intended purpose of the medical device type
1	AK30C	Amikacin 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
2	AP2C	Ampicillin 2ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
3	AP10C	Ampicillin 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
4	SAM20C	Ampicillin 10ug/Sulbactam 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
5	AUG3C	Amoxicillin/clavulanic acid 2-1	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
6	AUG30C	Amoxicillin/clavulanic acid 20-10	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
7	ATH15C	Azithromycin 15ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
8	ATM30C	Aztreonam 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
9	BA10C	Bacitracin 10 units	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
10	PY100C	Carbenicillin 100ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
11	CFC30C	Cefaclor 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
12	CFB30C	Ceftibuten 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
13	CMD30C	Cefamandole 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
14	CDX30C	Cefadroxil 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
15	BPR5C	Ceftobiprole 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
16	CPM30C	Cefepime 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
17	CFM5C	Cefixime 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
18	CPZ75C	Cefoperazone 75ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
19	CTX5C	Cefotaxime 5ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
20	CTX30C	Cefotaxime 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges



Serial No.	Device ID Number	Product Description	Method of use	Pack Size	Brand Name	Intended purpose of the medical device type
22	CTF30C	Cefotiam 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
22	FOX30C	Cefoxitin 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
23	CPD10C	Cefpodoxime 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
24	CZL30	Cefprozil 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
25	CPT5C	Ceftaroline 5ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
26	CPT30C	Ceftaroline 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
27	CZA14C	Ceftazidime/avibactam 10-4	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
28	CZA50C	Ceftazidime/avibactam 30-20	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
29	CAZ10C	Ceftazidime 10ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
30	CAZ30C	Ceftazidime 30ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
31	CRO5C	Ceftriaxone 5ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
32	CRO30C	Ceftriaxone 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
33	C/T40C	Ceftolozone/Tazobactam 30-10	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
34	CXM30C	Cefuroxime 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
35	CFX30C	Cephalexin 30ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
36	KF30C	Cephalothin 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
37	CZ30C	Cephazolin 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
38	C30C	Chloramphenicol 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
39	CIP5C	Ciprofloxacin 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
40	CLA15C	Clarithromycin 15ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
41	CD2C	Clindamycin 2ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
42	DLX5C	Delafloxacin 5ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
43	DOR10C	Doripenem 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges



Serial No.	Device ID Number	Product Description	Method of use	Pack Size	Brand Name	Intended purpose of the medical device type
44	DXT30C	Doxycycline 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
45	ERV20C	Eravacycline 20ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
46	ETP10C	Ertapenem 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
47	E15C	Erythromycin 15ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
48	FOT200C	Fosfomycin/Trometamol 200ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
49	FC10C	Fusidic Acid 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
50	FDC30C	Cefiderocol 30ug discs	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
51	GM10C	Gentamicin 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
52	GM30C	Gentamicin 30ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
53	GM120C	Gentamicin 120ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
54	IMI10C	Imipenem 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
55	IMR35C	Imipenem/relebactam 35µg discs	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
56	K30C	Kanamycin 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
57	LEV5C	Levofloxacin 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
58	LZD10C	Linezolid 10ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
59	LZD30C	Linezolid 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
60	MEC10C	Mecillinam 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
61	MEM10C	Meropenem 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
62	MEM10	Meropenem 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
63	MEV30C	Meropenem/Vaborbactam 20-10ug	EUCAST/CLSI	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
64	MZ5C	Metronidazole 5ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
65	MZ5	Metronidazole 5ug	CLSI	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
66	MN30C	Minocycline 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
67	MFX5C	Moxifloxacin 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges



Serial No.	Device ID Number	Product Description	Method of use	Pack Size	Brand Name	Intended purpose of the medical device type
68	MUP200C	Mupirocin 200ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
69	NA30C	Nalidixic Acid 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
70	NA30	Nalidixic Acid 30ug	EUCAST/CLSI	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
71	NE10C	Neomycin 10ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
72	NET30C	Netilmicin 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
73	NI100C	Nitrofurantoin 100ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
74	NI300C	Nitrofurantoin 300ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
75	NIB30C	Nitroxoline 30ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
76	NOR10C	Norfloxacin 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
77	NO5C	Novobiocin 5ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
78	OFX5C	Ofloxacin 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
79	OX1C	Oxacillin 1ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
80	OX5C	Oxacillin 5ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
81	OX1	Oxacillin 1ug	EUCAST/CLSI	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
82	PEF5C	Pefloxacin 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
83	PG1C	Penicillin G 1 unit	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
84	PG1	Penicillin G 1 unit	EUCAST	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
85	PG10C	Penicillin G 10 unit	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
86	PG10	Penicillin G 10 unit	CLSI	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
87	PRL30C	Piperacillin 30ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
88	PRL100C	Piperacillin 100ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
89	PTZ36C	Piperacillin/Tazobactam 30-6	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
90	PTZ110C	Piperacillin/Tazobactam 100-10	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
91	SYN15C	Quinupristin/dalfopristin 15ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
92	RP5C	Rifampicin 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges



Serial No.	Device ID Number	Product Description	Method of use	Pack Size	Brand Name	Intended purpose of the medical device type
93	RP5	Rifampicin 5ug	EUCAST/CLSI	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
94	SPC100C	Spectinomycin 100ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
95	S10C	Streptomycin 10ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
96	S300C	Streptomycin 300ug Discs	EUCAST	5x50 discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
97	TEC30C	Teicoplanin 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
98	TEL15C	Telithromycin 15ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
99	TEM30C	Temocillin 30ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
100	T30C	Tetracycline 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
101	TC75C	Ticarcillin 75ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
102	TGC15C	Tigecycline 15ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
103	TIM85C	Timentin 85ug (Ticarcillin 75ug/Clavulanic acid 10ug)	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
104	TN10C	Tobramycin 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
105	TM5C	Trimethoprim 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
106	TS25C	Cotrimoxazole 25ug (Trimethoprim 1.25ug/Sulphamethosazole 23.75ug)	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
107	TS25	Cotrimoxazole 25ug (Trimethoprim 1.25ug/Sulphamethosazole 23.75ug)	EUCAST/CLSI	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
108	VA5C	Vancomycin 5ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
109	VA5	Vancomycin 5ug	EUCAST	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
110	VA30C	Vancomycin 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Mast Group Ltd
Mast House, Derby Road
Bootle
Liverpool
L20 1EA
United Kingdom

Holds Certificate Number:

FM 724380

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

Design, manufacture and supply of in-vitro diagnostic devices and associated services.

For and on behalf of BSI:



Matt Page, Managing Director Assurance - UK & Ireland

Original Registration Date: 1994-06-14

Latest Revision Date: 2021-12-03

Effective Date: 2021-11-11

Expiry Date: 2024-05-31



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Certificate No: FM 724380

Location	Registered Activities
Mast Group Ltd Mast House, Derby Road Bootle Liverpool L20 1EA United Kingdom	Design, manufacture and supply of in-vitro diagnostic devices and associated services.
Mast Group Ltd Atlantic House, Derby Road Bootle Liverpool L20 1EA United Kingdom	Manufacturing, QC and warehousing of IVD kits and reagents, bacteriological media and other kits and reagents for the life sciences industry.



Original Registration Date: 1994-06-14
Latest Revision Date: 2021-12-03

Effective Date: 2021-11-11
Expiry Date: 2024-05-31

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Mast Group Ltd
Mast House, Derby Road
Bootle
Liverpool
L20 1EA
United Kingdom

Holds Certificate Number:

MD 724379

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, manufacture and supply of in-vitro diagnostic devices for clinical microbiology and molecular biology and bacteriological media.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-10-07

Latest Revision Date: 2021-11-28

Effective Date: 2021-06-01

Expiry Date: 2024-05-31

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Certificate No: **MD 724379**

Location	Registered Activities
Mast Group Ltd Mast House, Derby Road Bootle Liverpool L20 1EA United Kingdom	Design, manufacture and supply of in-vitro diagnostic devices for clinical microbiology and molecular biology and bacteriological media
Mast Group Ltd Atlantic House, Derby Road Bootle Liverpool L20 1EA United Kingdom	Manufacture of IVD kits and reagents for clinical microbiology and molecular biology, bacteriological media.



Original Registration Date: 2020-10-07

Latest Revision Date: 2021-11-28

Effective Date: 2021-06-01

Expiry Date: 2024-05-31

Certificate of CE-Notification

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

Monocent Inc.
9237 Eton Ave.,
Chatsworth, CA 91311
United States

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 with the Dutch Competent Authority with registration number:

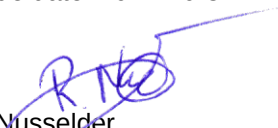
IVD Devices groups:	Registration number:
CLIA Test Kits	NL-CA002-2020-50897
ELISA Test Kits	NL-CA002-2020-50898
IFA Test Kits	NL-CA002-2020-50899
Instruments	NL-CA002-2020-50900
PCR Test Kits	NL-CA002-2020-50901
Rapid Tests	NL-CA002-2020-50902
Serology Test Kits	NL-CA002-2020-50903

see appendix

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: 2022-10-31

This Certificate of CE-Notification is valid until May 26, 2025


R. Nusselder
Sr. consultant CEpartner4U BV

C e p a r t n e r 4 U
Esdoornlaan13
3951 DB Maarn NL
tel: +31 (0)343 442 524
www.cepartner4u.nl

Appendix

List of devices.

CLIA Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
Allergy Assays					
IgE	CL3-5055	Low Risk	C	30275	2020-04-14
Thyroid Assays					
T3	CL3-5028	Low Risk	C	30312	2020-04-14
T4	CL3-5029	Low Risk	C	30314	2020-04-14
TSH	CL2-5030	Low Risk	C	30318	2020-04-14
T3 Uptake	CL3-5072	Low Risk	C	30313	2020-04-14
FT3	CL3-5026	Low Risk	C	30309	2020-04-14
FT4	CL3-5027	Low Risk	C	30308	2020-04-14
Tg (Thyroglobulin)	CL3-5073	Low Risk	C	30490	2020-04-14
TBG	CL3-5074	Low Risk	C	30316	2020-04-14
Anti-Tg	CL3-5075	Low Risk	C	30490	2020-04-14
Anti-TPO	CL3-5076	Low Risk	C	30317	2020-04-14
Ultra-Sensitive TSH	CL2-5077	Low Risk	C	30318	2020-04-14
Fertility Assays					
LH	CL3-5006	Low Risk	C	38965	2020-04-14
FSH	CL3-5004	Low Risk	C	30322	2020-04-14
Prolactin	CL3-5008	Low Risk	C	30325	2020-04-14
hCG	CL2-5005	Low Risk	B	30513	2020-04-14
AMH	CL3-5069	Low Risk	C	43148	2020-04-14
Beta hCG	CL2-5055	Low Risk	B	30332	2020-04-14
HGH	CL3-5007	Low Risk	C	30333	2020-04-14
PAPP-A	CL3-5068	Low Risk	C	31533	2020-04-14
Diabetes Assays					
Insulin	CL2-5003	Low Risk	C	30338	2020-04-14
C-peptide	CL2-5002	Low Risk	C	30336	2020-04-14
Tumor Markers Assays					
AFP	CL3-5031	Low Risk	C	30295	2020-04-14
CEA	CL3-5036	Low Risk	C	30288	2020-04-14
Free Beta hCG	CL2-5037	Low Risk	C	30333	2020-04-14
Beta 2 Microglobulin	CL2-5032	Low Risk	C	30296	2020-04-14
NSE	CL2-5039	Low Risk	C	30301	2020-04-14
CA-12-5	CL3-5034	Low Risk	C	30283	2020-04-14
CA-19-9	CL2-5035	Low Risk	C	30280	2020-04-14
CA-15-3	CL2-5033	Low Risk	C	30279	2020-04-14
Ferritin	CL3-5001	Low Risk	C	30377	2020-04-14
Cyfra21-1	CL2-5079	Low Risk	C	44431	2020-04-14
Pro-GRP	CL2-5080	Low Risk	C	44438	2020-04-14
PAP	CL2-5081	Low Risk	C	34226	2020-04-14
Steroid Assays					
Progesterone	CL3-5021	Low Risk	C	30294	2020-04-14
Estradiol	CL3-5016	Low Risk	C	30321	2020-04-14
Testosterone	CL3-5022	Low Risk	C	30327	2020-04-14

CLIA Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
Free Testosterone	CL9-5023	Low Risk	C	30327	2020-04-14
Testosterone (Saliva)	CL9-5025	Low Risk	C	30327	2020-04-14
5a-Androstane-3a, 17b-diol Glucuronide (3a- Diol G)	CL9-5009	Low Risk	C	31533	2020-04-14
17 OH Progesterone	CL3-5010	Low Risk	C	30324	2020-04-14
Androstenedione	CL3-5070	Low Risk	C	30319	2020-04-14
Aldosterone	CL3-5011	Low Risk	C	31428	2020-04-14
Cortisol	CL3-5012	Low Risk	C	31394	2020-04-14
DHEA	CL3-5013	Low Risk	C	39894	2020-04-14
DHEA-S	CL3-5014	Low Risk	C	39894	2020-04-14
uE3	CL3-5041	Low Risk	C	30330	2020-04-14
Estriol (Saliva)	CL9-5018	Low Risk	C	30329	2020-04-14
Estrone (Saliva)	CL9-5019	Low Risk	C	33293	2020-04-14
Estrone	CL3-5020	Low Risk	C	33293	2020-04-14
Plasma Renin Activity (PRA)	CL9-5024	Low Risk	C	43444	2020-04-14
SHBG	CL3-5071	Low Risk	C	30326	2020-04-14
Procalcitonin	CL3-5067	Low Risk	C	12069016	2020-04-14
Infectious Disease Assays					
Digoxin	CL3-5059	Low Risk	C	30386	2020-04-14
hs-CRP	CL2-5060	Low Risk	C	30499	2020-04-14
CK-MB	CL3-5061	Low Risk	C	30499	2020-04-14
Myoglobin	CL3-5062	Low Risk	C	30264	2020-04-14
cTn I	CL2-5063	Low Risk	C	30266	2020-04-14
Bone Metabolism					
ACTH	CL3-5017	Low Risk	C	39005	2020-04-14
Calcitonin	CL3-5064	Low Risk	C	30342	2020-04-14
PTH	CL3-5065	Low Risk	C	30353	2020-04-14
Vitamin D	CL3-5066	Low Risk	C	30350	2020-04-14
Autoimmune Disease					
Cardiolipin IgA	CL2-5051	Low Risk	C	30475	2020-04-14
Cardiolipin IgG	CL2-5052	Low Risk	C	30475	2020-04-14
Cardiolipin IgM	CL2-5053	Low Risk	C	30475	2020-04-14
ds-DNA	CL2-5054	Low Risk	C	30458	2020-04-14
RF IgM	CL2-5114	Low Risk	C	30500	2020-04-14
B2GP1 IgA	CL2-5115	Low Risk	C	30478	2020-04-14
B2GP1 IgG	CL2-5116	Low Risk	C	30478	2020-04-14
B2GP1 IgM	CL2-5117	Low Risk	C	30478	2020-04-14
Thyroglobulin IgG	CL2-5118	Low Risk	C	30315	2020-04-14
Anti-CCP	CL2-5119	Low Risk	C	44202	2020-04-14
Anemia Assays					
Folate	CL3-5056	Low Risk	C	30378	2020-04-14
Vitamin B12	CL3-5057	Low Risk	C	30384	2020-04-14
Transferrin Soluble Receptor (sTfR)	CL3-5058	Low Risk	C	30253	2020-04-14
NeoNatal Assays					
Neonatal TSH	CL2-5078	Low Risk	C	30310	2020-04-14

CLIA Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
Infectious Disease Assays					
H. pylori IgA	CL2-5048	Low Risk	B	30691	2020-04-14
H. pylori IgG	CL2-5049	Low Risk	B	30691	2020-04-14
H. pylori IgM	CL2-5050	Low Risk	B	30691	2020-04-14
H. pylori IgG (Quantitative)	CL2-5082	Low Risk	B	30691	2020-04-14
H. pylori Antigen	CL2-5083	Low Risk	B	30691	2020-04-14
EBV VCA IgA	CL2-5084	Low Risk	D	30809	2020-04-14
EBV VCA IgG	CL2-5085	Low Risk	D	30809	2020-04-14
EBV VCA IgM	CL2-5086	Low Risk	D	30809	2020-04-14
EBV EA-D IgA	CL2-5087	Low Risk	D	30809	2020-04-14
EBV EA-D IgG	CL2-5088	Low Risk	D	30809	2020-04-14
EBV EA-D IgM	CL2-5089	Low Risk	D	30809	2020-04-14
EBNA IgA	CL2-5090	Low Risk	D	30808	2020-04-14
EBNA IgG	CL2-5091	Low Risk	D	30808	2020-04-14
EBNA IgM	CL2-5092	Low Risk	D	30808	2020-04-14
Measles IgG	CL2-5093	Low Risk	C	44019	2020-04-14
Measles IgM	CL2-5094	Low Risk	C	44019	2020-04-14
VZV IgG	CL2-5095	Low Risk	C	44027	2020-04-14
VZV IgM	CL2-5096	Low Risk	C	44027	2020-04-14
Mumps IgG	CL2-5097	Low Risk	C	33908	2020-04-14
Mumps IgM	CL2-5098	Low Risk	C	33908	2020-04-14
Dengue IgG	CL2-5099	Low Risk	C	32481	2020-04-14
Dengue IgM	CL2-5100	Low Risk	C	32481	2020-04-14
HSV 1/2 IgG	CL2-5101	Low Risk	C	40176	2020-04-14
HSV 1/2 IgM	CL2-5102	Low Risk	C	40176	2020-04-14
HSV 1 IgA	CL2-5103	Low Risk	C	38870	2020-04-14
HSV 1 IgG	CL2-5104	Low Risk	C	38870	2020-04-14
HSV 1 IgM	CL2-5105	Low Risk	C	38870	2020-04-14
HSV 2 IgA	CL2-5106	Low Risk	C	38875	2020-04-14
HSV 2 IgG	CL2-5107	Low Risk	C	38875	2020-04-14
HSV 2 IgM	CL2-5108	Low Risk	C	38875	2020-04-14

ELISA Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
Allergy					
Total Human IgE	EL1-1000, EL2-1000	Low Risk	B	30275	2020-04-14
Human Specific IgG	EL15-1001	Low Risk	C	44211	2020-04-14
Human Specific IgG4	EL15-1002	Low Risk	C	44211	2020-04-14
Histamine	EL30-1003	Low Risk	C	30274	2020-04-14
Anemia					
Vitamin B12	EL1-1007	Low Risk	B	30384	2020-04-14
Folate	EL1-1005	Low Risk	B	30378	2020-04-14
sTfR-Transferrin Soluble Receptor	EL3-1006	Low Risk	B	30253	2020-04-14
Ferritin	EL1-1004	Low Risk	B	30377	2020-04-14

ELISA Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
Hepcidin	EL1-1008	Low Risk	B	12070190	2020-04-14
Autoimmune Disease					
Anti-CCP	EL2-1011	Low Risk	B	44202	2020-04-14
Anti-CP IgG	EL20-1288	Low Risk	B	44202	2020-04-14
Beta 2 Glycoprotein 1 IgA	EL2-1017	Low Risk	B	30478	2020-04-14
Beta 2 Glycoprotein 1 IgG	EL2-1018	Low Risk	B	30478	2020-04-14
Beta 2 Glycoprotein 1 IgM	EL2-1019	Low Risk	B	30478	2020-04-14
Anti-Tissue Transglutaminase IgG	EL20-1015	Low Risk	C	44385	2020-04-14
Anti-Tissue Transglutaminase IgA	EL20-1014	Low Risk	C	44385	2020-04-14
ANA Screen IgG	EL1-1009	Low Risk	B	30454	2020-04-14
ENA IgG Profile-6	EL10-1024	Low Risk	B	30455	2020-04-14
ENA Screen IgG	EL20-1025	Low Risk	B	30455	2020-04-14
Rheumatoid Factor (RF) IgA	EL15-1034	Low Risk	B	30500	2020-04-14
Rheumatoid Factor (RF) IgG	EL15-1035	Low Risk	B	30500	2020-04-14
Rheumatoid Factor (RF) IgM	EL2-1038	Low Risk	B	30500	2020-04-14
Sm/RNP IgG	EL1-1040	Low Risk	B	30464	2020-04-14
Sm IgG	EL1-1041	Low Risk	B	17276	2020-04-14
Jo-1 IgG	EL21-1029	Low Risk	C	30461	2020-04-14
Scl-70 IgG	EL1-1039	Low Risk	B	30463	2020-04-14
SS-A (Ro)	EL1-1042	Low Risk	B	44202	2020-04-14
SS-B (La)	EL1-1043	Low Risk	B	44202	2020-04-14
dsDNA	EL1-1023	Low Risk	B	30458	2020-04-14
Cardiolipin IgG	EL1-1021	Low Risk	C	30475	2020-04-14
Cardiolipin IgM	EL1-1022	Low Risk	C	30475	2020-04-14
Cardiolipin IgA	EL1-1020	Low Risk	C	30475	2020-04-14
Cardiolipin Total Ab	EL1-1044	Low Risk	C	30475	2020-04-14
Mitochondrial Antibody (MA)	EL1-1031	Low Risk	C	30476	2020-04-14
Thyroglobulin Antigen (Anti-Tg)	EL3-1016	Low Risk	C	30315	2020-04-14
PR3 (c-ANCA)	EL20-1033	Low Risk	B	30484	2020-04-14
ANCA screen IgG	EL10-1010	Low Risk	B	30483	2020-04-14
MPO, Myeloperoxidase (p-ANCA)	EL20-1032	Low Risk	B	30483	2020-04-14
Gliadin IgG	EL36-1026	Low Risk	C	30480	2020-04-14
Gliadin IgA	EL36-1027	Low Risk	C	30480	2020-04-14
TPO	EL1-1012	Low Risk	C	30317	2020-04-14
Anti-Phospholipids Screen	EL20-1013	Low Risk	B	30582	2020-04-14
ASMA	EL29-1302	Low Risk	B	30274	2020-04-14
Beta-2-Glycoprotein IgA	EL2-1017	Low Risk	B	30478	2020-04-14
Beta-2-Glycoprotein IgG	EL2-1018	Low Risk	B	30478	2020-04-14
Beta-2-Glycoprotein IgM	EL2-1019	Low Risk	B	30478	2020-04-14
Tumor markers					
Prostatic Acid Phosphatase (PAP)	EL2-1289	Low Risk	C	34226	2020-04-14
Beta-2-Microglobulin	EL2-1277	Low Risk	C	30296	2020-04-14
AFP (Alpha Fetoprotein)	EL1-1276	Low Risk	C	43480	2020-04-14
CEA	EL1-1283	Low Risk	C	30288	2020-04-14
CA-15-3	EL1-1279	Low Risk	C	30279	2020-04-14
CA-12-5	EL1-1278	Low Risk	C	30283	2020-04-14

ELISA Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
CA-19-9	EL1-1280	Low Risk	C	30280	2020-04-14
NSE	EL2-1286	Low Risk	C	30301	2020-04-14
Free Beta HCG	EL1-1284	Low Risk	C	30333	2020-04-14
Pro-GRP (Gastrin-Releasing Peptide)	EL2-1290	Low Risk	C	44438	2020-04-14
Chromogranin A	EL1-1281	Low Risk	C	30289	2020-04-14
HE4	EL1-1306	Low Risk	C	30289	2020-04-14
Cyfra21-1	EL2-1034	Low Risk	C	30289	2020-04-14
Bone Metabolism					
Intact PTH	EL3-1048	Low Risk	C	30353	2020-04-14
25-OH Vitamin D	EL1-1045	Low Risk	B	30350	2020-04-14
ACTH	EL3-1046	Low Risk	C	39005	2020-04-14
Cardiac					
Digoxin	EL3-1051	Low Risk	C	30386	2020-04-14
CK-MB	EL3-1050	Low Risk	C	30499	2020-04-14
Troponin I	EL1-1054	Low Risk	C	30266	2020-04-14
Myoglobin	EL6-1053	Low Risk	C	30264	2020-04-14
C-Reactive Protein (CRP)	EL1-1049	Low Risk	C	30499	2020-04-14
Diabetes					
Insulin	EL1-1058	Low Risk	C	30338	2020-04-14
C-peptide	EL1-1055	Low Risk	C	30336	2020-04-14
Leptin	EL9-1059	Low Risk	B	12069017	2020-04-14
Adiponectin	EL9-1056	Low Risk	B	12069017	2020-04-14
(IGFBP-1) Insulin-Like Growth Factor Binding Protein-1	EL9-1057	Low Risk	B	42852	2020-04-14
Anti-GAD	EL8-1060	Low Risk	B	30340	2020-04-14
IAA	EL8-1061	Low Risk	B	30339	2020-04-14
IGF-1	EL8-1062	Low Risk	B	30361	2020-04-14
Pro-Insulin	EL1-1063	Low Risk	C	42852	2020-04-14
Fertility					
Human Growth Hormone (HGH)	EL1-1083	Low Risk	B	30333	2020-04-14
hCG Visual	EL6-1082	Low Risk	B	30513	2020-04-14
Beta hCG (Total)	EL2-1078	Low Risk	B	30332	2020-04-14
FSH	EL1-1080	Low Risk	B	31533	2020-04-14
LH	EL1-1084	Low Risk	B	38246	2020-04-14
Prolactin	EL1-1086	Low Risk	B	30325	2020-04-14
PAPP-A	EL3-1085	Low Risk	B	31533	2020-04-14
SHBG	EL3-1261	Low Risk	B	30326	2020-04-14
AMH	EL3-1079	Low Risk	B	43148	2020-04-14
hCG	EL1-1081	Low Risk	B	30332	2020-04-14
Sperm Ab	EL8-1087	Low Risk	B	30486	2020-04-14
Infectious Diseases					
Adenovirus IgG	EL15-1102	Low Risk	C	39468	2020-04-14
Adenovirus IgA	EL15-1101	Low Risk	C	39468	2020-04-14
Adenovirus IgM	EL15-1103	Low Risk	C	39468	2020-04-14
Influenza A IgA	EL15-1365	Low Risk	B	39463	2020-04-14
Influenza A IgG	EL15-1366	Low Risk	B	39463	2020-04-14

ELISA Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
Influenza A IgM	EL15-1367	Low Risk	B	39463	2020-04-14
Influenza B IgA	EL15-1368	Low Risk	B	39463	2020-04-14
Influenza B IgG	EL15-1369	Low Risk	B	39463	2020-04-14
Influenza B IgM	EL15-1370	Low Risk	B	39463	2020-04-14
Chikungunya IgG	EL4-1114	Low Risk	D	32481	2020-04-14
Chikungunya IgM	EL4-1113	Low Risk	D	32481	2020-04-14
COVID-19 IgA	EL45-1373	Low Risk	D	42994	2020-04-14
COVID-19 IgG	EL1-1360	Low Risk	D	42994	2020-04-14
COVID-19 IgM	EL1-1361	Low Risk	D	42994	2020-04-14
COVID-19 IgG	EL36-1360R	Low Risk	D	42994	2020-04-14
COVID-19 IgM	EL36-1361R	Low Risk	D	42994	2020-04-14
COVID-19 IgG	EL45-1360	Low Risk	D	42994	2020-04-14
COVID-19 IgM	EL45-1361	Low Risk	D	42994	2020-04-14
COVID-19 Total Ab	EL45-1379	Low Risk	D	42994	2020-12-06
Mycobacterium Tuberculosis (TB) IgA	EL15-1317	Low Risk	C	30635	2020-04-14
Mycobacterium Tuberculosis (TB) IgG	EL15-1201	Low Risk	C	30635	2020-04-14
Mycobacterium Tuberculosis (TB) IgM	EL15-1202	Low Risk	C	30635	2020-04-14
Herpes Simplex 1 IgG (HSV1 IgA)	EL2-1162	Low Risk	C	38870	2020-04-14
Herpes Simplex 1 IgG (HSV1 IgG)	EL1-1163	Low Risk	C	38870	2020-04-14
Herpes Simplex 1 IgM (HSV1 IgM)	EL1-1164	Low Risk	C	38870	2020-04-14
Herpes Simplex 2 IgG (HSV2 IgG)	EL1-1165	Low Risk	C	38875	2020-04-14
Herpes Simplex 2 IgM (HSV2 IgM)	EL1-1166	Low Risk	C	38875	2020-04-14
Herpes Simplex 1,2 IgG (HSV1,2 IgG)	EL1-1167	Low Risk	C	40176	2020-04-14
Herpes Simplex 1,2 IgM (HSV1,2 IgM)	EL1-1168	Low Risk	C	40176	2020-04-14
Epstein Barr Virus VCA IgA (EBV, VCA IgA)	EL2-1135	Low Risk	D	30809	2020-04-14
Epstein Barr Virus VCA IgG (EBV, VCA IgG)	EL1-1136	Low Risk	D	30809	2020-04-14
Epstein Barr Virus VCA IgM (EBV, VCA IgM)	EL1-1137	Low Risk	D	30809	2020-04-14
Epstein Barr Virus Early Antigen (EA) IgM	EL2-1134	Low Risk	D	30809	2020-04-14
Epstein Barr Virus Early Antigen (EA) IgG	EL2-1133	Low Risk	D	30809	2020-04-14
Epstein Barr Virus Early Antigen (EA) IgA	EL2-1132	Low Risk	D	30809	2020-04-14
Epstein Barr Virus Nuclear Antigen (EBNA) IgG	EL2-1130	Low Risk	D	30808	2020-04-14
Epstein Barr Virus Nuclear Antigen (EBNA) IgM	EL2-1131	Low Risk	D	30808	2020-04-14
Epstein Barr Virus Nuclear Antigen (EBNA) IgA	EL2-1129	Low Risk	D	30808	2020-04-14
Measles IgG	EL1-1177	Low Risk	C	44019	2020-04-14
Measles IgM	EL1-1178	Low Risk	C	44019	2020-04-14
Mumps IgG	EL1-1179	Low Risk	C	33908	2020-04-14
Mumps IgM	EL1-1180	Low Risk	C	33908	2020-04-14
Mycoplasma pneumonia IgG	EL1-1181	Low Risk	C	30657	2020-04-14
Mycoplasma pneumonia IgM	EL1-1182	Low Risk	C	30657	2020-04-14
Syphilis (TPA) IgG	EL1-1195	Low Risk	C	30685	2020-04-14
Syphilis (TPA) IgM	EL1-1197	Low Risk	C	30685	2020-04-14
Legionella urine Ag detection	EL16-1175	Low Risk	C	30692	2020-04-14
H. pylori IgG	EL1-1140	Low Risk	B	30691	2020-04-14
H. pylori IgA	EL1-1139	Low Risk	B	30691	2020-04-14
H-Pylori IgM	EL1-1141	Low Risk	B	30691	2020-04-14
H. pylori Antigen	EL2-1138	Low Risk	B	30691	2020-04-14

ELISA Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
	EL32-1138				
Varicella-Zoster IgG	EL1-1209	Low Risk	C	44027	2020-04-14
Varicella-Zoster IgM	EL1-1210	Low Risk	C	44027	2020-04-14
HEV IgG	EL13-1156	Low Risk	C	30757	2020-04-14
HEV IgM	EL13-1161	Low Risk	C	30758	2020-04-14
HAV Ab	EL7-1142	Low Risk	C	30721	2020-04-14
HAV IgM	EL7-1143	Low Risk	C	30722	2020-04-14
HDV IgG	EL7-1153	Low Risk	D	30750	2020-04-14
HDV IgM	EL7-1155	Low Risk	D	30752	2020-04-14
HDV Ab	EL13-1315	Low Risk	D	30750	2020-04-14
HDV Ag	EL13-1316, EL7-1154	Low Risk	D	30747	2020-04-14
HTLV 1 + 2 Ab	EL7-1160	Low Risk	C	30789	2020-04-14
Lyme Disease IgG	EL10-1171	Low Risk	C	30697	2020-04-14
Lyme Disease IgM	EL10-1172	Low Risk	C	30697	2020-04-14
Lyme Disease IgG, M	EL10-1173	Low Risk	C	30697	2020-04-14
Bordetella Pertussis IgA	EL15-1110	Low Risk	C	37723	2020-04-14
Bordetella Pertussis IgG	EL15-1111	Low Risk	C	37723	2020-04-14
Bordetella Pertussis IgM	EL15-1112	Low Risk	C	37723	2020-04-14
RSV IgA	EL15-1186	Low Risk	B	30814	2020-04-14
RSV IgG	EL15-1187	Low Risk	B	30814	2020-04-14
RSV IgM	EL15-1188	Low Risk	B	30814	2020-04-14
Tetanus	EL5-1205	Low Risk	C	38876	2020-04-14
Diphtheria IgG	EL5-1124	Low Risk	D	33499	2020-04-14
Salmonella typhi IgG	EL1-1193	Low Risk	C	30709	2020-04-14
Salmonella typhi IgM	EL1-1194	Low Risk	C	30709	2020-04-14
Salmonella Antigen detection	EL4-1192	Low Risk	C	30709	2020-04-14
Anthrax IgG	EL1-1105	Low Risk	C	32481	2020-04-14
Babesia IgG	EL4-1109	Low Risk	C	32481	2020-04-14
Dengue IgM	EL5-1127	Low Risk	C	32481	2020-04-14
Dengue IgG/IgM	EL5-1125	Low Risk	C	32481	2020-04-14
Dengue IgG	EL5-1126	Low Risk	C	32481	2020-04-14
Dengue NS1 Antigen	EL4-1128	Low Risk	C	32481	2020-04-14
Japanese Encephalitis IgG	EL4-1169	Low Risk	C	44321	2020-04-14
Japanese Encephalitis IgM	EL4-1170	Low Risk	C	44321	2020-04-14
Leprosy IgG/IgM	EL4-1176	Low Risk	C	32481	2020-04-14
Parvovirus B19 IgG	EL30-1183	Low Risk	C	40443	2020-04-14
Parvovirus B19 IgM	EL30-1184	Low Risk	C	40444	2020-04-14
Rotavirus (fecal)	EL16-1185	Low Risk	C	30815	2020-04-14
Scrub Typhus IgG	EL4-1199	Low Risk	C	44028	2020-04-14
Scrub Typhus IgM	EL4-1200	Low Risk	C	44028	2020-04-14
TB IgA	EL15-1317	Low Risk	C	30635	2020-04-14
TB IgG	EL15-1201	Low Risk	C	30635	2020-04-14
TB IgM	EL15-1202	Low Risk	C	30635	2020-04-14
Zika Virus IgG	EL1-1203	Low Risk	C	32481	2020-04-14
Zika Virus IgM	EL1-1204	Low Risk	C	32481	2020-04-14

ELISA Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
West Nile IgG	EL4-1211	Low Risk	C	42926	2020-04-14
West Nile IgM	EL4-1212	Low Risk	C	42926	2020-04-14
Parasitology					
Schistosoma IgG	EL5-1227	Low Risk	C	30824	2020-04-14
Chagas	EL5-1213	Low Risk	D	30820	2020-04-14
Cysticercosis IgG (T. solium)	EL5-1220	Low Risk	B	39979	2020-04-14
Campylobacter	EL16-1229	Low Risk	B	33948	2020-04-14
E. coli 0157 Ag detection	EL16-1232	Low Risk	B	37727	2020-04-14
E. histolytica IgG (Amebiasis)	EL5-1221	Low Risk	B	39979	2020-04-14
E. histolytica Dispar	EL16-1233	Low Risk	B	39979	2020-04-14
Echinococcus IgG	EL5-1222	Low Risk	B	30822	2020-04-14
Fasciola IgG	EL5-1216	Low Risk	B	34068	2020-04-14
Fasciola gigantica	EL5-1217	Low Risk	B	34068	2020-04-14
Filaria IgG4	EL4-1218	Low Risk	B	34068	2020-04-14
Leishmania	EL5-1223	Low Risk	C	30823	2020-04-14
Leptospira IgG	EL5-1224	Low Risk	C	30716	2020-04-14
Leptospira IgM	EL5-1226	Low Risk	C	30716	2020-04-14
Leptospira IgG/IgM	EL5-1225	Low Risk	C	30716	2020-04-14
Toxocara IgG	EL5-1228	Low Risk	C	34068	2020-04-14
Trichinella IgG	EL5-1215	Low Risk	C	33379	2020-04-14
Ascaris IgG	EL5-1219	Low Risk	B	39979	2020-04-14
Strongyloides IgG	EL5-1214	Low Risk	C	34068	2020-04-14
Crypto/Giardia Ag detection	EL16-1230	Low Risk	B	30675	2020-04-14
Cryptosporidium Ag detection	EL16-1231	Low Risk	B	30675	2020-04-14
Giardia antigen	EL16-1235	Low Risk	B	36173	2020-04-14
Giardia coprpantigen in stool	EL5-1361	Low Risk	B	36173	2020-04-14
Anti-Giardia IgA ELISA in saliva	EL5-1362	Low Risk	B	36173	2020-04-14
Entamoeba histolytica coproantigen in stool	EL5-1363	Low Risk	B	39979	2020-04-14
Adenovirus Antigen	EL16-1104	Low Risk	C	41274	2020-04-14
Steroid					
Aldosterone	EL3-1247	Low Risk	C	31428	2020-04-14
Cortisol	EL1-1249	Low Risk	C	31394	2020-04-14
Aldosterone	EL3-1247	Low Risk	B	31428	2020-04-14
Cortisol	EL1-1249	Low Risk	C	31394	2020-04-14
Cortisol Saliva	EL9-1250	Low Risk	C	31394	2020-04-14
Estradiol	EL1-1254	Low Risk	B	30321	2020-04-14
DHEA-S	EL1-1251	Low Risk	C	30320	2020-04-14
DHEA	EL3-1252	Low Risk	C	39894	2020-04-14
Progesterone	EL1-1259	Low Risk	C	30323	2020-04-14
Progesterone Saliva	EL9-1260	Low Risk	C	30294	2020-04-14
Testosterone	EL1-1263	Low Risk	B	30327	2020-04-14
Testosterone Saliva	EL9-1265	Low Risk	B	30327	2020-04-14
Free Testosterone	EL1-1264	Low Risk	B	30327	2020-04-14
Androstenedione	EL1-1248	Low Risk	C	30321	2020-04-14
Free Estriol	EL1-1257	Low Risk	B	30330	2020-04-14
Dihydrotestosterones (DHT)	EL9-1253	Low Risk	C	30327	2020-04-14

ELISA Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
17-OH Progesterone	EL1-1245	Low Risk	C	30324	2020-04-14
5a-Androstane-3a, 17b-diol Glucuronide (3a- Diol G)	EL9-1246	Low Risk	C	31533	2020-04-14
Total Estrogen	EL9-1255	Low Risk	B	38858	2020-04-14
Estrone	EL3-1256	Low Risk	B	33293	2020-04-14
Pregnenolone	EL9-1258	Low Risk	B	33301	2020-04-14
Total Estriol	EL8-1266	Low Risk	B	30330	2020-04-14
Thyroid					
T3	EL1-1270	Low Risk	C	30314	2020-04-14
T4	EL1-1271	Low Risk	C	30312	2020-04-14
TSH	EL1-1273	Low Risk	C	30489	2020-04-14
U-TSH	EL6-1275	Low Risk	C	30489	2020-04-14
Free T4	EL1-1268	Low Risk	C	30308	2020-04-14
Free T3	EL1-1267	Low Risk	C	30309	2020-04-14
Reverse T3	EL9-1274	Low Risk	C	30311	2020-04-14
T Uptake	EL3-1269	Low Risk	C	30313	2020-04-14
Tg (Thyroglobulin)	EL1-1272	Low Risk	C	30490	2020-04-14
TBG (Thyroxine-Binding Globulin)	EL3-1262	Low Risk	C	30316	2020-04-14
Neo-Natal Panel					
Neo-Natal T4	EL1-1240	Low Risk	C	30273	2020-04-14
Neo-Natal TSH	EL1-1239	Low Risk	C	30310	2020-04-14
Neo-Natal TBG	EL3-1242	Low Risk	C	30316	2020-04-14
Neo-Natal 17-OH Progesterone	EL1-1236	Low Risk	C	30324	2020-04-14
Neo-Natal MSUD	EL1-1237	Low Risk	C	30273	2020-04-14
Neo-Natal PKU	EL1-1238	Low Risk	C	30273	2020-04-14
Neo-Natal IRT	EL1-1241	Low Risk	C	30273	2020-04-14
Neo-Natal Total Galactose	EL1-1243	Low Risk	C	30273	2020-04-14
G6PD	EL1-1303	Low Risk	C	30273	2020-04-14
Neo-Natal Biotinidase	EL1-1244	Low Risk	C	30273	2020-04-14
Others					
Procalcitonin	EL3-1309	Low Risk	C	12069016	2020-04-14
Calcitonin	EL3-1292	Low Risk	C	30342	2020-04-14
Renin	EL9-1300	Low Risk	B	43444	2020-04-14

IFA Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
Autoimmune Diseases and others					
ANA Rat Liver IFA Kit	IF17-4002, IF17-4019	Low Risk	C	41420	2020-04-14
ANA Mouse Kidney IFA Kit	IF17-4003	Low Risk	C	41420	2020-04-14
ANA Hep-2 IFA Kit	IF17-4004, IF17-4005, IF17-4018	Low Risk	C	17269	2020-04-14
AMA IFA Kit	IF17-4022, IF17-4023	Low Risk	C	17267	2020-04-14
AAS Rat Kidney Stomach Liver Tissue	IF17-4000	Low Risk	C	30274	2020-04-14

IFA Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
ASMA IFA Kit	IF17-4006, IF17-4015	Low Risk	C	30274	2020-04-14
ATA IFA Kit	IF17-4030, IF174031	Low Risk	C	30274	2020-04-14
ASA IFA Kit	IF17-4008, IF17-4034	Low Risk	C	30274	2020-04-14
nDNA IFA Kit	IF17-4007, IF17-4051, IF17-4052	Low Risk	C	30274	2020-04-14
Endomysial (Primate Endomysial)	IF17-4032, IF17-4033	Low Risk	C	12109016	2020-04-14
Anti-Reticulin IgA	IF17-4041, IF17-4042	Low Risk	C	30526	2020-04-14
Anti-Reticulin IgG	IF17-4043, IF17-4044	Low Risk	C	30526	2020-04-14
C-ANCA	IF17-4059	Low Risk	C	30484	2020-04-14
P-ANCA	IF17-4060	Low Risk	C	30483	2020-04-14
Bacterial Diseases					
Legionella pneumophila 1-6 IFA Poly (HT)	IF17-4063, IF17-4064	Low Risk	C	30694	2020-04-14
Legionella pneumophila 1-6/bdglmj/C Specimen	IF17-4061	Low Risk	C	30694	2020-04-14
Legionella pneumophila 1-6/bdglmj DFA Screen	IF17-4062	Low Risk	C	30694	2020-04-14
FTA-ABS Double Stain (Syphilis) IFA Kit	IF17-4013, IF17-4066	Low Risk	C	32455	2020-04-14
FTA-ABS (T. pallidum)	IF17-4012, IF17-4067	Low Risk	C	32455	2020-04-14
FTA-ABS (Syphilis) Titrable IFA Kit	IF17-4014	Low Risk	C	32455	2020-04-14
Viral diseases					
HSV-1 IgG IFA Kit	IF17-4016	Low Risk	C	39502	2020-04-14
HSV-2 IgG IFA Kit	IF17-4080	Low Risk	C	39502	2020-04-14
HSV-1 IgM IFA Kit	IF17-4017	Low Risk	C	39502	2020-04-14
HSV-2 IgM IFA Kit	IF17-4081	Low Risk	C	39502	2020-04-14
HSV 1&2 IgG	IF17-4078	Low Risk	C	39502	2020-04-14
HSV 1&2 IgM	IF17-4079	Low Risk	C	39502	2020-04-14
EBV-VCA IgG IFA Kit	IF17-4074	Low Risk	C	33971	2020-04-14
EBV-VCA IgM IFA Kit	IF17-4075	Low Risk	C	33971	2020-04-14
EBV-EA IFA Kit	IF17-4077	Low Risk	C	33971	2020-04-14
EBNA IFA Kit	IF17-4076	Low Risk	C	33971	2020-04-14
RMSF Rocky Mountain Spotted Fever (R. rickettsii)	IF17-4065	Low Risk	C	32473	2020-04-14
Measles IgG IFA Kit	IF17-4092	Low Risk	C	44019	2020-04-14
Measles IgM IFA Kit	IF17-4093	Low Risk	C	44019	2020-04-14
Mumps IgG IFA Kit	IF17-4094	Low Risk	C	33908	2020-04-14
Mumps IgM IFA Kit	IF17-4095	Low Risk	C	33908	2020-04-14
RSV IgG (Respiratory Syncytial Virus)	IF17-4096	Low Risk	C	30814	2020-04-14

IFA Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
RSV IgM (Respiratory Syncytial Virus)	IF17-4097	Low Risk	C	30814	2020-04-14
Varicella-Zoster Virus IgG IFA Kit	IF17-4098	Low Risk	C	44027	2020-04-14
Varicella-Zoster Virus IgM IFA Kit	IF17-4099	Low Risk	C	44027	2020-04-14
West Nile Virus IgG	IF17-4100	Low Risk	C	42926	2020-04-14
West Nile Virus IgG	IF17-4101	Low Risk	C	42926	2020-04-14

RT-PCR	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
SARS-CoV-2	PR31-8000	Low Risk	D	42994	2020-04-14
SARS-CoV-2	PR4-8000	Low Risk	D	42994	2020-04-14
SARS-CoV-2 pap-PCR	PR45-8000	Low Risk	D	42994	2020-12-06
SARS-CoV-2/Flu/RSV RT-PCR	PR31-8001	Low Risk	D	42994	2020-12-06

Rapid Tests Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
Tumor Markers Tests					
FOB Cassette	RT27-2182	Low Risk	C	38217	2020-04-14
FOB Strip	RT27-2181	Low Risk	C	38217	2020-04-14
CEA	RT27-2180	Low Risk	C	30288	2020-04-14
AFP	RT27-2179	Low Risk	C	30295	2020-04-14
Cardiac markers					
CK-MB Cassette (Serum/Plasma/Whole Blood)	RT27-2001	Low Risk	C	30499	2020-04-14
C-Reactive Protein (CRP) Cassette (Serum/Plasma/Whole Blood)	RT27-2003	Low Risk	C	30507	2020-04-14
C-Reactive Protein (CRP) Strip (Serum/Plasma/Whole Blood)	RT27-2002	Low Risk	C	30507	2020-04-14
D-Dimer Cassette (Plasma/Whole Blood)	RT27-2004	Low Risk	C	30576	2020-04-14
Myoglobin Cassette (Serum/Plasma/Whole Blood)	RT27-2005	Low Risk	C	30264	2020-04-14
Troponin I Cassette (Serum/Plasma/Whole Blood)	RT27-2007	Low Risk	C	30509	2020-04-14
3 in 1 Troponin I/Myoglobin/CKMB Cassette (Serum/Plasma/Whole Blood)	RT27-2006	Low Risk	C	42649	2020-04-14
Drug Test					
Alcohol Urine Strip	RT27-2010	Low Risk	B	30443	2020-04-14
Alcohol Saliva Strip	RT27-2009	Low Risk	B	30443	2020-04-14
Amphetamine Urine Cassette	RT27-2012	Low Risk	C	30516	2020-04-14
Amphetamine Urine Strip	RT27-2011	Low Risk	C	30516	2020-04-14
Barbiturates Urine Cassette	RT27-2014	Low Risk	C	30517	2020-04-14
Barbiturates Urine Strip	RT27-2013	Low Risk	C	30517	2020-04-14
Buprenorphine Urine Cassette	RT27-2016	Low Risk	C	31584	2020-04-14
Buprenorphine Urine Strip	RT27-2015	Low Risk	C	31584	2020-04-14
Benzodiazepine Urine Cassette	RT27-2018	Low Risk	C	30518	2020-04-14
Benzodiazepine Urine Strip	RT27-2017	Low Risk	C	30518	2020-04-14
Cocaine Urine Cassette	RT27-2022	Low Risk	C	30520	2020-04-14
Cocaine Urine Strip	RT27-2021	Low Risk	C	30520	2020-04-14

Rapid Tests Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
Cotinine Cassette	RT27-2024	Low Risk	C	37270	2020-04-14
Cotinine Strip	RT27-2023	Low Risk	C	37270	2020-04-14
EDDP Urine Cassette	RT27-2028	Low Risk	C	30521	2020-04-14
EDDP Urine Strip	RT27-2027	Low Risk	C	30521	2020-04-14
Fentanyl Urine Cassette	RT27-2030	Low Risk	C	31582	2020-04-14
Fentanyl Urine Strip	RT27-2029	Low Risk	C	31582	2020-04-14
Ketamine Urine Cassette	RT27-2032	Low Risk	C	31582	2020-04-14
Ketamine Urine Strip	RT27-2031	Low Risk	C	31582	2020-04-14
MDMA(Ecstasy) Cassette	RT27-2038	Low Risk	C	30423	2020-04-14
MDMA(Ecstasy) Strip	RT27-2037	Low Risk	C	30423	2020-04-14
Methadone (MTD) Urine Urine Cassette	RT27-2040	Low Risk	C	30521	2020-04-14
Methadone (MTD) Urine Urine Strip	RT27-2039	Low Risk	C	30521	2020-04-14
Methamphetamine Urine Cassette	RT27-2042	Low Risk	C	30423	2020-04-14
Methamphetamine Urine Strip	RT27-2041	Low Risk	C	30423	2020-04-14
Marijuana (THC) Urine Cassette	RT27-2057	Low Risk	C	30519	2020-04-14
Marijuana (THC) Urine Strip	RT27-2056	Low Risk	C	30519	2020-04-14
Opiates Urine Cassette	RT27-2044	Low Risk	C	30522	2020-04-14
Opiates Urine Strip	RT27-2043	Low Risk	C	30522	2020-04-14
Oxycodone Urine Cassette	RT27-2047	Low Risk	C	31584	2020-04-14
Oxycodone Urine Strip	RT27-2046	Low Risk	C	31584	2020-04-14
Phencyclidine (PCP) Urine Cassette	RT27-2049	Low Risk	C	30523	2020-04-14
Phencyclidine (PCP) Urine Strip	RT27-2048	Low Risk	C	30435	2020-04-14
Tricyclic Antidepressants (TCA) Cassette	RT27-2055	Low Risk	C	30524	2020-04-14
Tricyclic Antidepressants (TCA) Strip	RT27-2054	Low Risk	C	30523	2020-04-14
Tramadol Urine Cassette	RT27-2059	Low Risk	C	31582	2020-04-14
Tramadol Urine Strip	RT27-2058	Low Risk	C	31582	2020-04-14
2-Drug Cassette (Any Combination)	RT27-2060	Low Risk	C	30261	2020-04-14
3-Drug Cassette (Any Combination)	RT27-2061	Low Risk	C	30261	2020-04-14
4-Drug Cassette (Any Combination)	RT27-2062	Low Risk	C	30261	2020-04-14
5-Drug Cassette (Any Combination)	RT27-2063	Low Risk	C	30261	2020-04-14
6-Drug Cassette (Any Combination)	RT27-2064	Low Risk	C	30261	2020-04-14
7-Drug Cassette (Any Combination)	RT27-2065	Low Risk	C	30261	2020-04-14
8-Drug Cassette (Any Combination)	RT27-2066	Low Risk	C	30261	2020-04-14
9-Drug Cassette (Any Combination)	RT27-2067	Low Risk	C	30261	2020-04-14
10-Drug Cassette (Any Combination)	RT27-2068	Low Risk	C	30261	2020-04-14
11-Drug Cassette (Any Combination)	RT27-2069	Low Risk	C	30261	2020-04-14
12-Drug Cassette (Any Combination)	RT27-2070	Low Risk	C	30261	2020-04-14
2-Drug Strip (Any Combination)	RT27-2071	Low Risk	C	30261	2020-04-14
3-Drug Strip (Any Combination)	RT27-2072	Low Risk	C	30261	2020-04-14
4-Drug Strip (Any Combination)	RT27-2073	Low Risk	C	30261	2020-04-14
5-Drug Strip (Any Combination)	RT27-2074	Low Risk	C	30261	2020-04-14
6-Drug Strip (Any Combination)	RT27-2075	Low Risk	C	30261	2020-04-14
7-Drug Strip (Any Combination)	RT27-2076	Low Risk	C	30261	2020-04-14
8-Drug Strip (Any Combination)	RT27-2077	Low Risk	C	30261	2020-04-14
9-Drug Strip (Any Combination)	RT27-2078	Low Risk	C	30261	2020-04-14
10-Drug Strip (Any Combination)	RT27-2079	Low Risk	C	30261	2020-04-14

Rapid Tests Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
11-Drug Strip (Any Combination)	RT27-2080	Low Risk	C	30261	2020-04-14
12-Drug Strip (Any Combination)	RT27-2081	Low Risk	C	30261	2020-04-14
Drug Test/Cup					
2-Drug Cup (Any Combination)	RT27-2082	Low Risk	C	30261	2020-04-14
3-Drug Cup (Any Combination)	RT27-2083	Low Risk	C	30261	2020-04-14
4-Drug Cup (Any Combination)	RT27-2084	Low Risk	C	30261	2020-04-14
5-Drug Cup (Any Combination)	RT27-2085	Low Risk	C	30261	2020-04-14
6-Drug Cup (Any Combination)	RT27-2086	Low Risk	C	30261	2020-04-14
7-Drug Cup (Any Combination)	RT27-2087	Low Risk	C	30261	2020-04-14
8-Drug Cup (Any Combination)	RT27-2088	Low Risk	C	30261	2020-04-14
9-Drug Cup (Any Combination)	RT27-2089	Low Risk	C	30261	2020-04-14
10-Drug Cup (Any Combination)	RT27-2090	Low Risk	C	30261	2020-04-14
11-Drug Cup (Any Combination)	RT27-2091	Low Risk	C	30261	2020-04-14
12-Drug Cup (Any Combination)	RT27-2092	Low Risk	C	30261	2020-04-14
Infectious Diseases and others					
Legionella Urinary Antigen Cassette	RT27-2147	Low Risk	C	30692	2020-04-14
Legionella Urinary Antigen Strip	RT27-2146	Low Risk	C	30692	2020-04-14
Adeno/Rotavirus Antigen Cassette	RT27-2131	Low Risk	C	42994	2020-04-14
Adeno Antigen Cassette	RT27-2132	Low Risk	C	42994	2020-04-14
Rotavirus Antigen Cassette	RT27-2161	Low Risk	C	30815	2020-04-14
Chagas Cassette	RT27-2133	Low Risk	C	30820	2020-04-14
Chikungunya IgG/IgM Cassette	RT27-2135	Low Risk	C	42994	2020-04-14
Gonorrhoea Cassette	RT27-2140	Low Risk	C	38851	2020-04-14
Influenza A&B Cassette	RT27-2145	Low Risk	C	39466	2020-04-14
Leishmania IgG/IgM Cassette	RT27-2149	Low Risk	C	30823	2020-04-14
Leishmania Cutaneous Strip	RT27-2148	Low Risk	C	30823	2020-04-14
Leptospira IgG/IgM	RT27-2150	Low Risk	C	30716	2020-04-14
Syphilis Cassette	RT27-2172	Low Risk	C	30687	2020-04-14
Syphilis Strip	RT27-2173, RT24-2173	Low Risk	C	30687	2020-04-14
Mononucleosis Cassette (Mono) (S/P)	RT27-2177	Low Risk	C	30826	2020-04-14
Strep A Cassette	RT27-2169	Low Risk	C	30826	2020-04-14
Strep A Strip	RT27-2168	Low Risk	C	30826	2020-04-14
Strep B Cassette	RT27-2171	Low Risk	C	30827	2020-04-14
Strep B Strip	RT27-2170	Low Risk	C	30827	2020-04-14
H1N1 Strip	RT40-2209	Low Risk	C	39461	2020-04-14
H. Pylori Ab Cassette (Serum/Plasma)	RT27-2141	Low Risk	B	30825	2020-04-14
H. Pylori Ab Cassette (Serum/Plasma/Whole Blood)	RT27-2142, RT24-2142	Low Risk	B	30825	2020-04-14
H. Pylori Antigen Cassette	RT27-2143, RT24-2203	Low Risk	B	30689	2020-04-14
HAV IgM	RT27-2108	Low Risk	C	30720	2020-04-14
Dengue IgG&IgM	RT27-2138, RT24-2197	Low Risk	C	42994	2020-04-14
Dengue NS1	RT24-2139	Low Risk	C	42994	2020-04-14
Dengue IgG/IgM/NS1	RT24-2208	Low Risk	C	42994	2020-04-14

Rapid Tests Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
Malaria P.f./Pv	RT24-2204	Low Risk	C	30674	2020-04-14
Malaria Pan	RT24-2206	Low Risk	C	30674	2020-04-14
Malaria P.f./Pan	RT24-2205, RT27-2154	Low Risk	C	30674	2020-04-14
Malaria P.f. Cassette	RT24-2207, RT27-2151	Low Risk	C	30674	2020-04-14
Malaria P.f. Strip	RT27-2152	Low Risk	C	30674	2020-04-14
Malaria P.f./vivax	RT27-2153	Low Risk	C	30674	2020-04-14
Norovirus	RT27-2156	Low Risk	C	32459	2020-04-14
Salmonella typhi Antigen Cassette	RT27-2163	Low Risk	C	30709	2020-04-14
Salmonella typhi IgG/IgM Cassette	RT27-2164	Low Risk	C	30709	2020-04-14
Salmonella typhi/paratyphi antigen	RT27-2165	Low Risk	C	30709	2020-04-14
Scrub typhus IgG Strip	RT4-2166	Low Risk	C	30717	2020-04-14
Scrub typhus IgM Strip	RT4-2167	Low Risk	C	30717	2020-04-14
Zika Virus IgG/IgM Cassette	RT27-2178	Low Risk	C	42994	2020-04-14
COVID-19 IgG/IgM	RT24-2198, RT28-2198, RT45-2198	Low Risk	D	44022	2020-04-14
SARS-CoV2 Antigen Rapid Test	RT45-2214	Low Risk	D	44022	2020-08-24
Tuberculosis (TB) Cassette	RT27-2175	Low Risk	C	44020	2020-04-14
Tuberculosis (TB) Strip	RT27-2174	Low Risk	C	44020	2020-04-14
HEV IgG/IgM	RT27-2119	Low Risk	D	30756	2020-04-14
Cryptococcus Ag	RT27-2137	Low Risk	C	37746	2020-04-14
Hantavirus IgG/IgM	RT27-2144	Low Risk	C	15048014	2020-04-14
Mycoplasma pneumoniae Ag	RT27-2155	Low Risk	C	17311	2020-04-14
Rickettsia IgG/IgM	RT24-2160	Low Risk	C	30717	2020-04-14
RSV	RT27-2162	Low Risk	C	30814	2020-04-14
Tetanus	RT27-2176	Low Risk	C	38876	2020-04-14
Fertility					
FSH Urine Cassette	RT27-2094	Low Risk	B	30512	2020-04-14
FSH Urine Strip	RT27-2093	Low Risk	B	30512	2020-04-14
Ovulation					
LH Urine Cassette	RT27-2106	Low Risk	B	30515	2020-04-14
LH Urine Strip	RT27-2105	Low Risk	B	30515	2020-04-14
Pregnancy					
hCG 10 mIU/ml Midstream	RT27-2099	Low Risk	B	30513	2020-04-14
hCG 20 mIU/ml Midstream	RT27-2102	Low Risk	B	30513	2020-04-14
hCG 10mIU/ml urine Cassette	RT27-2095	Low Risk	B	30513	2020-04-14
hCG 10mIU/ml urine Strip	RT27-2097	Low Risk	B	30513	2020-04-14
hCG 10mIU/ml urine/serum	RT27-2098	Low Risk	B	30513	2020-04-14
hCG 20 mIU/ml urine Cassette	RT27-2101	Low Risk	B	30513	2020-04-14
hCG 20 mIU/ml urine Strip	RT27-2100	Low Risk	B	30513	2020-04-14
hCG 10mIU/ml urine/serum/p	RT27-2096	Low Risk	B	30513	2020-04-14
hCG 20 mIU/ml urine/serum/p Cassette	RT27-2104	Low Risk	B	30513	2020-04-14
hCG 20 mIU/ml urine/serum/p Strip	RT27-2103	Low Risk	B	30513	2020-04-14
Others					

Rapid Tests Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
Micro-Albumin (HAS) Strip	RT27-2197	Low Risk	C	30246	2020-04-14
Ferritin	RT27-2196	Low Risk	C	30377	2020-04-14
H-FABP	RT27-2107	Low Risk	C	1230190	2020-04-14
Nt-proBNP	RT27-1157	Low Risk	C	12130190	2020-04-14
Procalcitonin (S/P/WB)	RT27-2158	Low Risk	C	12069016	2020-04-14
Procalcitonin (S/P)	RT27-2159	Low Risk	C	12069016	2020-04-14
Urine Reagent Strips					
URS-1G	RT27-2185	Low Risk	B	17419	2020-04-14
URS-2PK	RT27-2186	Low Risk	B	30226	2020-04-14
URS-3 GKpH	RT27-2187	Low Risk	B	30226	2020-04-14
URS-4 GKpHB	RT27-2188	Low Risk	B	30226	2020-04-14
URS-5GKpHBP	RT27-2189	Low Risk	B	30226	2020-04-14
URS-6GKpHBPBili	RT27-2190	Low Risk	B	30226	2020-04-14
URS-7GKpHBPBiliU	RT27-2191	Low Risk	B	30226	2020-04-14
URS-8GKpHBPBiliUN	RT27-2192	Low Risk	B	30226	2020-04-14
URS-9GKpHBPBiliUNS	RT27-2193	Low Risk	B	30226	2020-04-14
URS-10GKpHBPBiliUNSL	RT27-2194	Low Risk	B	30226	2020-04-14
URS-11	RT27-2195	Low Risk	B	30226	2020-04-14

Serology Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
C- Reactive Protein (CRP)	SL25-3002, SL25-3003	Low Risk	C	30499	2020-04-14
RF	SL25-3008, SL25-3009	Low Risk	C	30500	2020-04-14
Anti- Streptolysin O(ASO)	SL25-3000, SL25-3001	Low Risk	C	30495	2020-04-14
Infectious Mononucleosis Screening (Mono)	SL25-3004, SL25-3005	Low Risk	C	30810	2020-04-14
RPR	SL25-3011, SL25-3012	Low Risk	C	17393	2020-04-14
Lupus Erythematosus (SLE)	SL25-3007	Low Risk	C	30487	2020-04-14
TPHA	SL25-3016	Low Risk	C	32453	2020-04-14
Rotavirus	SL25-3010	Low Risk	C	17381	2020-04-14
S. Aureus	SL25-3013	Low Risk	C	33887	2020-04-14
Streptococci Lancefield grouping	SL25-3015	Low Risk	C	17389	2020-04-14
VDRL Antigen	SL25-3017	Low Risk	C	17395	2020-04-14
PARATYPHOID A (Salmonella, flagellar a antigen)	SL25-3022	Low Risk	C	39453	2020-04-14
PARATYPHOID B (Salmonella, flagellar b antigen)	SL25-3023	Low Risk	C	39453	2020-04-14
PARATYPHOID C (Salmonella typhi, flagellar c antigen)	SL25-3024	Low Risk	C	39453	2020-04-14
SALMONELLA Group A Antigen (somatic antigen)	SL25-3028	Low Risk	C	39453	2020-04-14
SALMONELLA Group B Antigen (somatic antigen)	SL25-3029	Low Risk	C	39453	2020-04-14

Serology Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
SALMONELLA Group C Antigen (somatic antigen)	SL25-3030	Low Risk	C	39453	2020-04-14
TYPHOID H (Salmonella typhi, flagellar d antigen)	SL25-3031	Low Risk	C	39453	2020-04-14
TYPHOID O (Salmonella typhi, somatic Group D antigen)	SL25-3032	Low Risk	C	39453	2020-04-14
Brucella Melitensis	SL25-3018	Low Risk	C	39536	2020-04-14
Brucella Abortus	SL25-3019	Low Risk	C	39536	2020-04-14
PROTEUS OX2 (somatic antigen)	SL25-3026	Low Risk	C	39543	2020-04-14
PROTEUS OX19 (somatic antigen)	SL25-3025	Low Risk	C	39543	2020-04-14
PROTEUS OXK (somatic antigen)	SL25-3027	Low Risk	C	39543	2020-04-14



Certificate of Registration

This is to certify the Quality Management System of:

MONOCENT, INC.
9237 Eton Avenue
Chatsworth, CA 91311

has been assessed and found to be in compliance with the requirements of

ISO 9001:2015

for the following scope:

**Manufacturing and Distribution of IVD Products
(Serology, Rapid, ELISA, CLIA, IFA Test Systems and Instrumentation)**

IAF Code: 31 & 35

Certificate Number: **SARA-2019-CA-0253-01-A**

Originally Registered:
January 10, 2020

Latest Issue:
December 20, 2022

Certification Cycle:
January 10, 2023 – January 9, 2026

Expiration Date:
January 9, 2026

President, SARA Registrar



MSCB-194

This registration is subject to the company maintaining its system to the required standard which will be monitored annually by SARA Registrar. This certificate remains the property of Standards American Registrations Authority (SARA Registrar) and shall be returned immediately upon request.
SARA Registrar Headquarter Mailing: 1807H Santa Rita Road, #175, Pleasanton, CA 94566



Certificate of Registration

This is to certify the Quality Management System of:

MONOCENT, INC.

9237 Eton Avenue
Chatsworth, CA 91311

has been assessed and found to be in compliance with the requirements of

ISO 13485:2016

for the following scope:

**Manufacturing and Distribution of IVD Products
(Serology, Rapid, ELISA, CLIA, IFA Test Systems and Instrumentation)**

Medical Device Code: In Vitro Diagnostics (IVD) & Non-active Medical Device

Certificate Number: **SARA-2019-CA-0253-02-A**

Originally Registered:
January 10, 2020

Latest Issue:
December 20, 2022

Certification Cycle:
January 10, 2023 – January 9, 2026

Expiration Date:
January 9, 2026

President, SARA Registrar



MSCB-194

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SARA Registrar Headquarter Mailing: 1807H Santa Rita Road, #175, Pleasanton, CA 94566



ENGLISH

H. Pylori IgG ELISA TEST SYSTEM



REF **EL1-1140**



96 TESTS

IVD

INTENDED USE

Monocent, Inc.'s H. pylori IgG ELISA Test System is intended for the detection of IgG antibody to H. pylori in human serum and plasma.

SUMMARY AND EXPLANATION

H. pylori is detectable in nearly 100% of adult patients with duodenal ulcer and about 80% of patients with gastric ulcer. An association between H. pylori and gastric cancer is confirmed. In developing countries, where most children become infected by the age of 10, gastric cancer rates are very high. In the USA and other developed countries, standards of hygiene and the increasing socioeconomic status of the population have reduced the incidence of infection, and in parallel, the rates of peptic ulcers and gastric cancer have declined. There is excellent correlation between the clinical presentation of gastritis, the presence of H. pylori in the stomach and elevated serum H. pylori IgG antibody. ELISA sensitivity and specificity are 90%, and the predictive value of a negative result for is very high. H. pylori-specific IgG antibody falls significantly after successful antibacterial therapy. Eradication of H. pylori is associated with a significant reduction in duodenal ulcer recurrence. H. pylori strains are classified into two broad groups - those that express both VacA and CagA (type I) and those that produce neither (type II). Type I strains are predominating in patients with ulcers and cancer. Up to 50% of adults is infected with H. pylori, but most of them are asymptomatic and will not develop ulcer. The reason is they are infected with type II. 80-100% of patients with duodenal ulcer disease produce CagA antibodies against a 128 kd antigen compared with 60-63% of H. pylori-infected persons with gastritis only, indicating that serologic

responses to the 128 kd protein are more prevalent among H. pylori-infected persons with duodenal ulcers than infected persons without peptic ulceration. In H. pylori-infected patients who develop gastric cancer, serum IgG against CagA 94% sensitive and 93% specific, indicating that detection of antibodies to CagA is useful marker for diagnosis of duodenal ulcer and gastric cancer.

PRINCIPLE OF THE TEST

Diluted patient serum is added to wells coated with purified antigen. IgG specific antibody, if present, binds to the antigen. All unbound materials are washed away and the enzyme conjugate is added to bind to the antibody-antigen complex, if present. Excess enzyme conjugate is washed off and substrate is added. The plate is incubated to allow the hydrolysis of the substrate by the enzyme. The intensity of the color generated is proportional to the amount of IgG specific antibody in the sample.

MATERIALS AND COMPONENTS

- Microwells coated with H. pylori antigen (12x8x1)
- Sample Diluent: 1 bottle (ready to use) (22ml)
- Calibrator: 1 Vial (ready to use) (1ml)
- Positive Control: 1 vial (ready to use) (1ml)
- Negative Control: 1 vial (ready to use) (1ml)
- Enzyme conjugate: 1 bottle (ready to use) (12ml)
- TMB Substrate: 1 bottle (ready to use) (12ml)
- Stop Solution: 1 bottle (ready to use) (12ml)
- Wash concentrate 20X: 1 bottle (25ml)

MATERIALS REQUIRED BUT NOT PROVIDED

- Distilled or deionized water
- Precision pipettes
- Disposable pipette tips
- ELISA reader capable of reading absorbance at 450nm
- Absorbance paper or paper towel
- Graph paper

STORAGE CONDITIONS

- Store the kit at 2-8 °C.
- Keep microwells sealed in a dry bag with desiccants.
- The reagents are stable until expiration of the kit.
- Do not expose test reagents to heat, sun or strong light

PRECAUTIONS

1. Potential biohazardous materials:
2. The calibrator and controls contain human source components which have been tested and found non-reactive for hepatitis B surface antigen as well as HIV antibody with FDA licensed reagents. However, as there is no test method that can offer complete assurance that HIV, Hepatitis B virus or other infectious agents are absent, these reagents should be handled at

the Biosafety Level 2, as recommended in the Centers for Disease Control/National Institutes of Health manual, "Biosafety in Microbiological and Biomedical Laboratories." 1984.

3. Optimal results will be obtained by strict adherence to the test protocol. Precise pipetting as well as following the exact time and temperature requirements is essential.
4. Do not pipette by mouth. Do not smoke, eat, or drink in the areas in which specimens or kit reagents are handled.
5. The components in this kit are intended for use as an integral unit. The components of different lots should not be mixed.
6. Control sera and sample diluent contain preserved with sodium azide. Sodium azide may react with lead and copper plumbing to form explosive metal azide. On disposal, flush with a large volume of water.

SPECIMEN COLLECTION

1. Collect blood specimens and separate the serum.
2. Specimens may be refrigerated at 2-8 °C for up to seven days or frozen for up to six months. Avoid repetitive freezing and thawing.

REAGENT PREPARATION

Prepare 1x wash buffer by adding the contents of the bottle (25 ml, 20x) to 475 ml of distilled or deionized water. Store at room temperature (20-25 °C).

TEST PROCEDURE

Bring all specimen and reagents o room temperature and gently mix.

1. Place the desired number of coated strips into the holder.
2. Negative control, positive control, and calibrator are ready to use. Prepare 1:21 dilution of test samples, by adding 10 µl of the sample to 200 µl of sample diluent. Mix well.
3. Dispense 100 µl of diluted sera, calibrator and controls into the appropriate wells. For the reagent blank, dispense 100µl sample diluent in 1a well position. Tap the holder to remove air bubbles from the liquid and mix well. Incubate for 20 minutes at room temperature.
4. Remove liquid from all wells. Wash wells three times with 300 µl of 1x wash buffer. Blot on absorbance paper or paper towel.
5. Dispense 100 µl of enzyme conjugate to each well and incubate for 20 minutes at room temperature.
6. Remove enzyme conjugate from all wells. Wash wells three times with 300 µl of 1x wash buffer. Blot on absorbance paper or paper towel.
7. Dispense 100 µl of TMB substrate and incubate for 10 minutes at room temperature. Add 100 µl of stop solution.
8. Read o.d. at 450 nm using ELISA reader within 15 min. A dual wavelength is recommended with reference filter of 600-650 nm.

CALCULATION OF RESULTS

1. Check Calibrator Factor (CF) value on the calibrator bottle. This value might vary from lot to lot. Make sure you check the value on every kit.
2. Calculate the cut-off value: Calibrator OD x Calibrator Factor (CF).
3. Calculate the Ab (Antibody) Index of each determination by dividing the O.D. value of each sample by cut-off value.

EXAMPLE OF RESULTS AND CALCULATIONS

Calibrator mean OD = 0.8
Calibrator factor (CF) = 0.5
Cut-off value = $0.8 \times 0.5 = 0.400$
Positive control OD = 1.2
Ab index = $1.2 / 0.4 = 3$
Patient sample OD = 1.6
Ab index = $1.6 / 0.4 = 4.0$

QUALITY CONTROL

The test run may be considered valid provided the following criteria are met:

1. The O.D. of the Calibrator should be greater than 0.250.
2. The Ab index for Negative control should be less than 0.9.
3. The Ab Index for Positive control should fall within the range specified on the COA/label.

INTERPRETATION

The following is intended as a guide to interpretation of *H. pylori* IgG test results; each laboratory is encouraged to establish its own criteria for test interpretation based on sample populations encountered.

Antibody Index Interpretation

- <0.9 No detectable antibody to *H. pylori* IgG by ELISA.
0.9-1.1 Borderline positive. Follow-up testing is recommended if clinically indicated.
>1.1 Detectable antibody to *H. pylori* IgG by ELISA

LIMITATIONS OF THE TEST

1. The test results obtained using this kit serve only as an aid to diagnosis and should be interpreted in relation to the patient's history, physical findings and other diagnostic procedures.
2. Lipemic or hemolyzed samples may cause erroneous results.

PERFORMANCE CHARACTERISTICS

1. Sensitivity

149 patient sera were tested by this *H. pylori* IgG ELISA and a reference ELISA method. 51 sera were positive and 91 were negative by both methods (95% agreement). The results are summarized below:

<i>H. pylori</i> IgG ELISA			
	+	-	Total
Reference ELISA Kit	51	4	55
	3	91	94
Total	54	95	149

2. Precision

Intra Assay Study

Serum	No. of Replicates	Mean	Standard Deviation	Coefficient of Variation %
1	16	2.52	0.127	5.04
2	16	1.30	0.037	2.84
3	16	0.59	0.044	7.45

Intra Assay Study

Serum	No. of Replicates	Mean	Standard Deviation	Coefficient of Variation %
1	10	1.34	0.090	6.57
2	10	0.97	0.066	6.80
3	10	0.18	0.017	9.44

REFERENCES

1. Cutler AF; Prasad VM; Santogade P. Four-year trends in *Helicobacter pylori* IgG serology following successful eradication. Am J Med 1998;105(1):18-20
2. Holtmann G; Talley NJ; Mitchell H; Hazell S. Antibody response to specific *H. pylori* antigens in functional dyspepsia, duodenal ulcer disease, and health. Am J Gastroenterol 1998; 93(8):1222-7.
3. Parsonnet J; Replogle M; Yang S; Hiatt R. Seroprevalence of CagA-positive strains among *Helicobacter pylori*-infected, healthy young adults. J Infect Dis 1997;175(5):1240-2.
4. Klaamas K; Held M; Wadström T; Lipping A; Kurtenkov O. IgG immune response to *Helicobacter pylori* antigens in patients with gastric cancer as defined by ELISA and immunoblotting. Int J Cancer 1996; 67(1):1-5.
5. Matsukura N; Onda M; Tokunaga A; Kato S; Yoshiyuki T; Hasegawa H; Yamashita K; Tomtitchong P; Hayashi A. Role of *Helicobacter pylori* infection in perforation of peptic ulcer: an age- and gender-matched case-control study. J Clin Gastroenterol 1997;10:S235-9.

 **Manufactured by
Monocent, Inc.**

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www.monocent.com

EC REP CEpartner4U

ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS.
www.cepartner4u.com

Revision Date: 2016/07/05

DICHIARAZIONE DI CONFORMITA'
Conformity declaration



Il sottoscritto, Rinaldo Ruggero legale rappresentante della ditta:
The undersigned, Rinaldo Ruggero legal representative of the company:

produttore/manufacturer

SYNTESYS S.a.s. di Rinaldo R. & C.

indirizzo/address

Via G. Galilei, 10/3 35037 Zona Industriale SELVE DI TEOLO (PADOVA) ITALY

o rappresentante il mandatario autorizzato entro la Unione Europea
or representing the authorized mandatary within the European Community

Mandatario autorizzato/authorized mandatary

indirizzo/address

Dichiara sotto la propria responsabilità che il prodotto/*declares under his own responsibility that the product:*

Denominazione/*Description*

Padella per ammalati, urinali uomo e donna, speculum vaginali, tamponcini cotonati, tamponi sterili in provetta, tamponi sterili con terreno Amies e Stuart in provetta/ *Bed pan, Urinal's man and woman, Vaginal speculum, Cotton swab, Sterile swab in test tube, Sterile swab with medium Amies or Stuart in test tube*

Materiale/*Material*

Polipropilene, Polietilene, Legno/ *Polypropylene, Polyethylene, Wood*

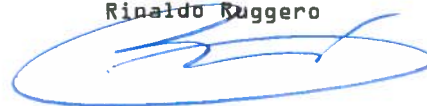
È conforme alle disposizioni della direttiva 93/42/CE e s.m., concernente i dispositivi medici ed al Decreto Legislativo di recepimento con D.lgs. del 24/02/1997 n° 46/97 e soddisfa a tutti i requisiti specificati.

Il dispositivo è stato classificato appartenente alla classe I° secondo i criteri stabiliti in base a quanto previsto dall'Art. 9 ed allegato IX della direttiva sopra citata /*It meets the EC Directive 93/42 about Medical Device, specifications established by the Italian law n 46/97, dated 24th February 1997. The device was classified as belonging to the 1st class, according to the specifications of the established by the art.9, IX enclosure of the above mentioned directive.*

Dichiara inoltre che la documentazione tecnica di supporto alla presente dichiarazione di conformità è conservata presso gli uffici dell'azienda e sarà posta alla disposizione di chi la richiede/ *declares that all technical documents attached to this conformity statment are filed in our company and can be consulted by any authorized body on demand.*

Data 07.01.2016
Issued on January 7th 2016

SYNTESYS S.A.S.
Il legale rappresentante
Rinaldo Ruggero





SYNTESYS



SYNTESYS S.A.S. DI RINALDO R. & C.

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DICHIARAZIONE DI CONFORMITA'

Conformity declaration



Il sottoscritto, Rinaldo Ruggero legale rappresentante della ditta:
The undersigned, Rinaldo Ruggero legal representative of the company:

produttore/manufacturer

SYNTESYS S.a.s. di Rinaldo Ruggero & C.

indirizzo/address

Via G. Galilei, 10/3 35037 Zona Industriale SELVE DI TEOLO (PADOVA) ITALY

o rappresentante il mandatario autorizzato entro la Unione Europea or representing the authorized mandatary within the European Community

Mandatario autorizzato/authorized mandatary

indirizzo/address

Dichiara sotto la propria responsabilità che il prodotto/*declares under his own responsibility that the product:*

Denominazione degli
articoli
prodotti/*Description of
Manufacturer*

Contenitori per urina, contenitori per feci,
contenitori universali, Pipette Pasteur, Piastre di
Petri, Anse Sterili per batteriologia, Aste a "L",
Puntali Eppendorf gialli e blue, cuvette per
spettrofotometro, tazzine per campionamento siero,
bacchette per distacco ed estrazione del coagulo,
pinzette in polistirolo monouso, provette monouso in
plastica, tappi alettati per provette diam. 12 mm e
16mm, provette con granuli ed acceleratore, provette
sottovuoto per prelievo, Sistema SEDIPLAST,
Microprovette, Portavetrini, Vetrini precolorati,
Portaprovette, supporti per microprovette, bottiglie
per raccolta urine.

*Urine container, faeces container, universal
container, Pasteur pipette, Petri dishes, Sterile
loops, Sterile loops open "L", Eppendorf tips yellow
and blue, cuvettes for spectrophotometer, samples
cups, Rod to detach clot, disposable forceps,
Disposable plastic tubes, winged stoppers for tubes
diam. 12mm & 16mm, Test tube with granules and clot
activator, vacuum test tube, SEDIPLAST system,
micro test tubes, Slides Mailer, "TESTSIMPLETS" slide
rack for test tubes, rack for micro test tubes,
Bottles for urine collection.*



SYNTESYS



SYNTESYS S.A.S. DI RINALDO R. & C.
VIA G. GALILEI, 10/3
35037 Z.I. SELVE DI TEOLO (PD)

TEL. +39 049 9903866 R.A. FAX +39 049 9903867

COD.FISCALE P.IVA N.REG.IMP. PADOVA 03573950288
E-MAIL INFO@SYNTESYS.IT - WEB WWW.SYNTESYS.IT

Materiale/Material

**Polipropilene, Polistirolo, Polietilene e
Polimetilmetacrilato**

***Polypropylene, Polystyrene, Polyethylene and
Polymethylmetacrylate***

È conforme alle disposizioni della direttiva 98/79/CE concernente i dispositivi medici diagnostici in vitro e recepito in Italia con D.L. del 08/09/2000 n° 332 allegato 1 (requisiti essenziali) ed è fabbricato in accordo ai requisiti di cui all'Allegato III della sopra citata direttiva / *It meets the CE Directive 98/79 CE about in vitro diagnostic device specifications established by the Italian law n. 332, dated 8th September 2000. The device is made according to the specifications of the III attached of the above-mentioned directive.*

Dichiara inoltre che la documentazione tecnica di supporto alla presente dichiarazione di conformità è conservata presso gli uffici dell'azienda e sarà posta alla disposizione di chi la richiede/*declares that all technical documents attached to this conformity statement are filed in our company and can be consulted by any authorized body on demand.*

Data 07/01/2016

Issued on January 7th 2016

SYNTESYS S.a.s.
Il legale rappresentante
Rinaldo Ruggero

 S GR11.1 DOC 180 REV02 OF 12/10/2020	CERTIFICATE OF STERILITY AND QUALITY ASSURANCE CERTIFICADO DE ESTERILIDAD Y GARANTÍA DE CALIDAD	N° 21- CRT03218
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CODE CÓDIGO	LOT N° N° DE LOTE	EXP. DATE FECHA DE CADUCIDAD
108C	210422500	31/03/2023

Device description:	TRANSYSTEM AMIES W/O CH PLASTIC APPLICATOR RAYON TIPPED
<i>Descripción del producto:</i>	TRANSYSTEM AMIES SIN CARBON HISOPO PLASTICO SENCILLO

Goods have been irradiated by gamma radiation.

The applied dose range is validated to guarantee the Sterility Assurance Level SAL 10⁻⁶.

Sterilisation procedure validated in conformity with BS EN ISO 11137-1:2015 and BS EN ISO 11137-2:2015.

El producto ha sido irradiado por radiación gamma.

La dosis media aplicada ha sido validada para asegurar el nivel de garantía de esterilidad SAL de 10⁻⁶.

El proceso de esterilización ha sido validado según las normas BS EN ISO 11137-1:2015 y BS EN ISO 11137-2:2015.

Goods has been manufactured according to the EN ISO 13485:2016 system.

El material ha sido fabricado según las normas EN ISO 13485:2016.

Medium Visual Appearance and Mechanical Controls: passed according to internal SOP.

Especificaciones de la apariencia visual y controles mecánicos del medio: apto según el protocolo (interno) normalizado de trabajo.

pH of the medium at 25°C acceptability limits 7.2 ± 0.3: passed

pH del medio a 25° C, límites de aceptabilidad 7,2±0,3: apto.

Microscopic Bioburden Specifications, maximum 2 micro-organisms per 20 microscopic fields at 10X100 magnification: passed.

Análisis microscópico Bioburden, máximo 2 microorganismos en 20 campos microscópicos con ampliación 10x100: apto.

Cultural Response: swabs were inoculated with the tester organisms (see the table) and placed in the medium. Recovery obtained after 24 hours at 20-25°C: passed.

Respuesta al cultivo: torundas inoculadas con organismos de prueba (ver tabla) e introducidas en el medio. Recuperación obtenida después de 24 horas a 20-25 °C: apto.

TRANSYSTEM AMIES AND STUART CLEAR GEL AND WITH CHARCOAL	TRANSYSTEM AMIES AND STUART LIQUID	TRANSYSTEM CARY BLAIR
<i>N. gonorrhoeae</i> ATCC 43069	<i>N. gonorrhoeae</i> ATCC 43069	<i>C. jejuni</i> ATCC 33291
<i>B. fragilis</i> ATCC 25285	<i>S. pyogenes</i> ATCC 19615	<i>E. coli</i> ATCC 25922
<i>H. influenza</i> ATCC 10211	<i>H. influenzae</i> ATCC 10211	<i>S. flexneri</i> ATCC 12022
/	/	<i>Y. enterocolitica</i> ATCC 9610

All reported results were obtained at time of Lot release.

Los citados resultados fueron obtenidos en el momento de la liberación del lote.

Copan Italia SpA certifies that all product quality requirements have been met and that all information stated above is correct.

Copan Italia SpA certifica la conformidad con todos los requisitos de calidad del producto y que toda la información arriba mencionada es correcta.

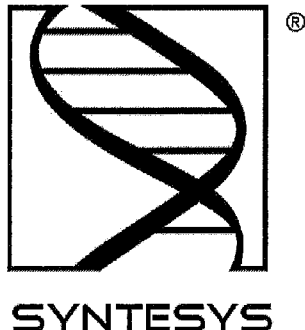
24/03/2021

Certificate Date of Issue
Fecha de expedición del certificado



Chief Quality Officer
Copan Italia SpA

Via F.Perotti, 10 – 25125 Brescia (Italy)



Cert. N.7111/2

Cert. N.6574/2

SYNTESYS S.R.L. UNIPERSONALE

VIA G. GALILEI, 10/3 - 35037 Z.I. SELVE DI TEOLO (PD)
TEL. +39 049 9903866 R.A. FAX +39 049 9903867
C.F./P.I./N.REG.IMP. PADOVA 03573950288
REA PD-320123 - CAP.SOC. 20.700,00€
E-MAIL INFO@SYNTESYS.IT - WEB WWW.SYNTESYS.IT
PEC POSTA@PEC.SYNTESYS.IT

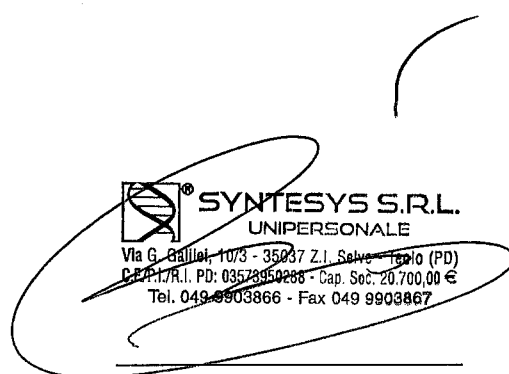
AUTHORIZATION LETTER

We, **Syntesys S.R.L.** having a registered office at Via G. Galilei 10/3, 35037 Selve di Teolo - PD - Italy, assign **Sanmedico SRL** having a registered office at A.Corobceanu str., apt. 9, Chişinău MD-2012, Moldova, as authorized representative.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

This letter is valid till 31.12.2021

Teolo, 05.01.2021



 **SYNTESYS S.R.L.**
UNIPERSONALE
Via G. Galilei, 10/3 - 35037 Z.I. Selve di Teolo (PD)
C.F./P.I./R.I. PD: 03573950288 - Cap. Soc. 20.700,00 €
Tel. 049.9903866 - Fax 049 9903867

Rinaldo Ruggero
CEO and Legal Representative
SYNTESYS S.R.L.

Certificate

CISQ/ICIM S.P.A. has issued an IQNet recognized certificate that the organization:

SYNTESYS S.R.L.

Head Office and Operative Unit

Via G. Galilei, 10/1-2-3 - Zona Industriale - I-35037 Selve di Teolo (PD)

Operative Units

Via G. Galilei, 16/1 - Zona Industriale - I-35037 Selve di Teolo (PD)

Via San Benedetto, 48/A - Zona Industriale - I-35037 Selve di Teolo (PD)

Via G. Galilei, 3 - Zona Industriale - I-35037 Selve di Teolo (PD)

has implemented and maintains a/an

Quality Management System

for the following scope:

Trading of products for laboratory analysis. Manufacturing of products for laboratory analysis and sanitary products. Design and production management of sterile swabs for the collection and the preservation of biological samples, also for surgical application, with or without transport medium.

which fulfils the requirements of the following standard:

ISO 9001:2015

Issued on: **2022-06-05**

First issued on: **2013-06-05**

Expires on: **2025-06-04**

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document.

Registration Number: **IT-83562**



Alex Stoichitoiu
President of IQNET



Mario Romersi
President of CISQ



This attestation is directly linked to the IQNET Member's original certificate and shall not be used as a stand-alone document.

IQNET Members*:

AENOR Spain **AFNOR Certification** France **APCER** Portugal **CCC** Cyprus **CISQ** Italy **CQC** China **CQM** China **CQS** Czech Republic
Cro Cert Croatia **DQS Holding GmbH** Germany **EAGLE Certification Group** USA **FCAV** Brazil **FONDONORMA** Venezuela **ICONTEC**
Colombia **ICS** Bosnia and Herzegovina **Inspecta Sertifointi Oy** Finland **INTECO** Costa Rica **IRAM** Argentina **JQA** Japan **KFQ** Korea
LSQA Uruguay **MIRTEC** Greece **MSZT** Hungary **Nemko AS** Norway **NSAI** Ireland **NYCE-SIGE** México **PCBC** Poland **Quality Austria**
Austria **SII** Israel **SIQ** Slovenia **SIRIM QAS International** Malaysia **SQS** Switzerland **SRAC** Romania **TSE** Turkey **YUQS** Serbia

* The list of IQNET Members is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

Certificate

CISQ/ICIM S.P.A. has issued an IQNet recognized certificate that the organization:

SYNTESYS S.R.L.

Head Office and Operative Unit

Via G. Galilei, 10/1-2-3 - Zona Industriale - I-35037 Selve di Teolo (PD)

Operative Units

Via G. Galilei, 16/1 - Zona Industriale - I-35037 Selve di Teolo (PD)

Via San Benedetto, 48/A - Zona Industriale - I-35037 Selve di Teolo (PD)

Via G. Galilei, 3 - Zona Industriale - I-35037 Selve di Teolo (PD)

has implemented and maintains a/an

Quality Management System

for the following scope:

Trading of products for laboratory analysis. Manufacturing of products for laboratory analysis and sanitary products. Design and production management of sterile swabs for the collection and the preservation of biological samples, also for surgical application, with or without transport medium.

which fulfils the requirements of the following standard:

ISO 13485:2016

Issued on: **2022-06-05**

First issued on: **2014-06-21**

Expires on: **2025-06-04**

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document.

Registration Number: **IT-93779**



Alex Stoichitoiu
President of IQNET



Mario Romersi
President of CISQ



This attestation is directly linked to the IQNET Member's original certificate and shall not be used as a stand-alone document.

IQNET Members*:

AENOR Spain **AFNOR Certification** France **APCER** Portugal **CCC** Cyprus **CISQ** Italy **CQC** China **CQM** China **CQS** Czech Republic
Cro Cert Croatia **DQS Holding GmbH** Germany **EAGLE Certification Group** USA **FCAV** Brazil **FONDONORMA** Venezuela **ICONTEC**
Colombia **ICS** Bosnia and Herzegovina **Inspecta Sertifointi Oy** Finland **INTECO** Costa Rica **IRAM** Argentina **JQA** Japan **KFQ** Korea
LSQA Uruguay **MIRTEC** Greece **MSZT** Hungary **Nemko AS** Norway **NSAI** Ireland **NYCE-SIGE** México **PCBC** Poland **Quality Austria**
Austria **SII** Israel **SIQ** Slovenia **SIRIM QAS International** Malaysia **SQS** Switzerland **SRAC** Romania **TSE** Turkey **YUQS** Serbia

* The list of IQNET Members is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

Declaration Ref No: DC21-0035

CE Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

We,

Atlas Medical

Head office: Ludwig-Erhard-Ring 3
Blankenfelde-Mahlow, Germany.
Tel: +49 - 33708 – 3550 30
Email: info@atlas-medical.com

Middle East Site: Sahab Free Zone Area, P. O. Box 212555, Amman, Jordan.
Tel.: +962 6 4026468
Fax: +962 6 4022588
Email: info@atlas-medical.com

Declare our responsibility that the following product:

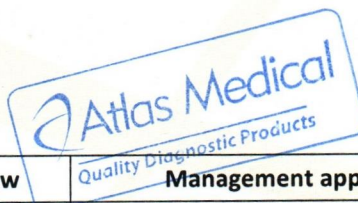
See Attached list

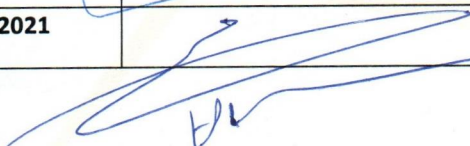
- Comply with all essential requirements (Annex I) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.
- This product is produced under Atlas quality system (ISO13485:2016) issued by GMED:
Certificate N°: 36655 rev 1
Expiry Date: October 8th.2023
- Comply with the essential requirements of following standards (EN 18113-1, -2, -4:2011, EN ISO 15223:2016, EN ISO 23640:2015, EN ISO 14971:2019, ISO 2859/1:1999, EN ISO 13612:2002, EN ISO 13641:2002).

And

Intended for In-Vitro Professional use only.

Manufacturer
Atlas Medical
Ludwig-Erhard-Ring 3
Blankenfelde-Mahlow , Germany.



Atlas Medical	Issue date	Date of review	Management approval	MRXDO10F.10 08.02.2011
	March.2021	09.03.2021		

CE Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

Product Description
8.00.02.0.0100 : ASO Latex Kit, 100 Tests (4ml Latex, 2x1.0ml controls).
8.00.00.0.0100: CRP Latex Kit, 100 Tests (4 ml Latex, 2x1.0 ml Controls)
8.00.04.0.0100: RF Latex Kit, 100 Tests (4ml Latex, 2x1.0ml controls)
8.00.17.0.0100: D-Dimer Latex Kit, 100 Tests
8.00.13.0.0300 : Streptococcus Latex Kit, 6 Groups, 6x50 Tests (5x1.5ml Latex (A,B,C,G,F), 1x3ml Latex(D), 1x1.0ml Positive Control, 1x2ml Extraction Reagent E, 1x1.5ml Extraction Reagent 1, 1x1.5ml Extraction Reagent 2, 2x2.5ml Extraction Reagent 3, Stirring Sticks, Glass Slide).
8.00.18.3.0500 : RPR Syphilis (Coarse Grain) Kit, 500 Tests (10 ml latex, 2x1ml control) Without card, stirring sticks.
8.00.18.3.1000 RPR Carbon Antigen (Coarse Grain) Kit, 1000 Tests (Reagent only).



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

TCS Biosciences Limited
Botolph Claydon
Buckingham
MK18 2LR
United Kingdom

Holds Certificate Number:

FS 28907

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

The procurement, manufacture, design, development and sale of a range of diagnostic products for clinical, pharmaceutical, food and environmental laboratory testing.

For and on behalf of BSI:



Matt Page, Managing Director Assurance - UK & Ireland

Original Registration Date: 1994-08-11

Latest Revision Date: 2022-01-14

Effective Date: 2022-01-27

Expiry Date: 2025-01-26



Page: 1 of 1

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Certificate of Registration

ENVIRONMENTAL MANAGEMENT SYSTEM - ISO 14001:2015

This is to certify that:

TCS Biosciences Ltd
Botolph Claydon
Buckingham
MK18 2LR
United Kingdom

Holds Certificate Number:

EMS 590359

and operates an Environmental Management System which complies with the requirements of ISO 14001:2015 for the following scope:

The procurement, manufacture, design, development and sale of a range of diagnostic products for clinical, pharmaceutical, food and environmental laboratory testing.



For and on behalf of BSI:

Matt Page, Managing Director Assurance - UK & Ireland

Original Registration Date: 2013-06-10

Latest Revision Date: 2022-01-14

Effective Date: 2022-01-27

Expiry Date: 2025-01-26



Page: 1 of 1

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