

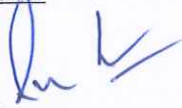
DECLARATION OF CONFORMITY**Manufacturer's Name:** MERIL DIAGNOSTICS PVT. LTD.**Manufacturer's Address:** Second Floor, D1-D3, Meril Park,
Survey No. 135/2/B & 174/2,
Muktanand Marg, Chala,
Vapi – 396191,
Gujarat, India.**Product Name:** _____
(The Immunology Reagents covered by this declaration are indicated in the Annex I)**Product Details:** Control No. DOC/IM/GEN/C/Rev.03/23.10.2019

Lot No.: _____ Mfg. Date: _____

Ref. No.: _____ Expiry Date: _____

Conforms to the applicable national and international standards.

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All the supporting documentations are retained under the premises of the manufacturer.

General applicable directives: DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices**List of Standard Applied:** EN 13975:2003, EN 13640:2002, EN 13641:2002, EN 13612 : 2002, EN 14136:2004, EN 980:2008, EN 1041:2008, EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 18113-1: 2011, EN ISO 18113-2 : 2011, EN 15193:2009, EN 15194:2009, EN 17511:2003, EN 23640:2015, ISO 15223-1:2016**Conformity Assessment Route:** Annex: III of Directive /98/79/EC on In vitro Diagnostic Medical Devices**Device Classification:** Device other than those covered in Annex II of Directive 98/79/EC**European Authorized Representative:** Obelis s.a.,
Bd General Wahis 53,
1030, Brussels, Belgium.
T +32.2.732.5954
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E mail@obelis.net**Signature:** **Name:** Mr. K. Sridhar**Designation:** Senior General Manager**Date/Location:** Date: _____ Location: Vapi, Gujarat, INDIA

Annex I

Sr. No.	Product Name	UMDNS Code	Product Code
1.	MERISCREEN hCG	19952	HCGRPD-01 RPDHCG-01 RPDHCG-02
2.	Merilisa T3 ELISA	19109	TTTELI-01
3.	Merilisa T4 ELISA	19110	TTFELI-01
4.	Merilisa TSH ELISA	19865	TSOELI-01
5.	Merilisa Cortisol ELISA	19131	COSELI-01
6.	Merilisa Free Estriol ELISA	19871	FESELI-01
7.	Merilisa Thyroglobulin ELISA	17398	ATGELI-01
8.	Merilisa Testosterone ELISA	19120	TSTELI-01
9.	Merilisa Estradiol ELISA	19115	ESTELI-01
10.	Merilisa Progesterone ELISA	19118	PSTELI-01
11.	Merilisa LH ELISA	19117	LHEELI-01
12.	Merilisa FSH ELISA	19116	FSNELI-01
13.	Merilisa 25OH Vitamin D Total ELISA	19142	VTDELI-01
14.	Merilisa Prolactin ELISA	19119	PRLELI-01
15.	Merilisa β HCG ELISA	19124	BHCELI-01
16.	Merilisa Free Testosterone ELISA	19869	FTSELI-01
17.	Merilisa FT3 ELISA	19862	FTTELI-01
18.	Merilisa FT4 ELISA	19111	FFFELI-01
19.	Merilisa DHEA-S ELISA	19114	DHSELI-01
20.	Merilisa Total IgE ELISA	17371	TIEELI-01
21.	Merilisa Insulin ELISA	19127	INSELI-01
22.	Merilisa C-Peptide ELISA	19126	CPTTELI-01
23.	Merilisa ANA Screen	19038	ANAELI-01
24.	Merilisa Anti Phospholipid Screen	20107	APLELI-01
25.	Merilisa Anti dsDNA IgG ELISA	20075	DSDELI-01
26.	Merilisa Anti Cardiolipin IgM ELISA	20108	ACMELI-01
27.	Merilisa Anti Cardiolipin IgG ELISA	20108	ACGELI-01
28.	Merilisa Anti Cardiolipin Screen	20108	ACSELI-01
29.	Merilisa 17-OH Progesterone ELISA	19868	HPSELI-01
30.	LumiQuant LH – CLIA	19117	LUT CLI-01
31.	LumiQuant FSH – CLIA	19116	FOL CLI-01
32.	LumiQuant PROLACTIN – CLIA	19119	PLC CLI – 01
33.	LumiQuant PROGESTERONE – CLIA	19118	PRGCLI – 01
34.	LumiQuant TESTOSTERONE – CLIA	19120	TES CLI-01
35.	LumiQuant ESTRADIOL – CLIA	19115	ESTCLI – 01
36.	LumiQuant C- PEPTIDE – CLIA	19126	PEP CLI – 01
37.	LumiQuant INSULIN – CLIA	19127	INSCLI – 01
38.	LumiQuant T3 – CLIA	19109	TTTCLI-01
39.	LumiQuant T4 – CLIA	19110	TTFCLI-01
40.	LumiQuant TSH CLIA	19865	TSHCLI-01
41.	LumiQuant FT3 CLIA	19862	FTTCLI-01
42.	LumiQuant FT4 CLIA	19111	FTFCLI-01
43.	LumiQuant Anti-TG CLIA	17280	ATGCLI-01
44.	LumiQuant Anti-TPO CLIA	20098	TPOCLI-01
45.	Merilisa Anti-TG ELISA	17280	ATGELI-01
46.	Merilisa Anti-TPO ELISA	20098	ATPELI-01
47.	MeriScreen Dengue IgG / IgM	22367	DTARPD-01 RPDDAB-01
48.	MeriScreen Dengue NS1 Ag	Not Available	DTNRPD-02 DTNRPD-03 RPDDAG-01
49.	MeriScreen Dengue Onset	Not Available	DTCRPD-01

			DTCRPD-02 RPDDON-01
50.	Merilisa i T3	19109	ITTELI-01
51.	Merilisa i T4	19110	ITFELI-01
52.	Merilisa i TSH	19865	TSIELI-01
53.	MeriScreen Malaria PAN Ag	19527	RPDMPN-01
54.	Merilisa Malaria Pan Ag (pLDH)	19527	MPNELI-02
55.	MeriScreen Syphiline	19471	SYPRPD-01 SYPRPD-02 RPDSYP-01 RPTSYP-02 RPTSYP-03 RPDSYP-02
56.	Makesure T3 ELISA	19109	ITTELI-02
57.	Makesure T4 ELISA	19110	ITEELI-02
58.	Makesure TSH ELISA	19865	TSIELI-02
59.	Merilisa i 25-OH Vitamin D ELISA	19142	VTDELI-01
60.	Merilisa Anti-CCP ELISA	9419	CCPELI-01
61.	Merilisa Anti-MPO (pANCA) ELISA	20114	AMAELI-01
62.	Merilisa Anti-PR3 (cANCA) ELISA	20113	APAELI-01
63.	Merilisa AFP-ELISA	17259	AFPELM-01
64.	Merilisa CEA-ELISA	17293	CEAELM-01
65.	LumiQuant CA 15-3 CLIA	Not Available	BRSCLI-01
66.	LumiQuant CA 19-9 CLIA	Not Available	PNCCLI-01
67.	LumiQuant CA 125 CLIA	Not Available	OVACLI-01
68.	LumiQuant CEA CLIA	Not Available	CEACLI-01
69.	LumiQuant AFP-CLIA	7594	AFPCLI-01
70.	Pregios One Step Test For Hcg	19952	HCGRRT-02
71.	i-can One step Pregnancy Test Device	19952	-
72.	MERISCREEN hCG Dipstick	19952	HCGSTK-01 HCGSTK-02 RSTHCG-01 RSTHCG-02
73.	RapidSure Dengue IgG/IgM	22367	RPDDAB-02
74.	RapidSure Dengue NS1	Not Available	RPDDAG-02
75.	RapidSure Dengue Duo NS1+IgG/IgM	Not Available	RPDDON-02