

E.A.R.-CERTIFICATE

(ART 10.3 of the Directive 98/79/EC on In Vitro Diagnostic)

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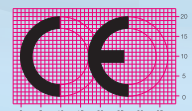
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Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001 : 2015 and ISO 13485 : 2016 certified in accordance to the profession of a European Authorized Representative.



Annex A - List of Devices

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

#	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN/EDMS Code	Class
1.	NCVPCR-01 NCVPCR-02	MERIL	COVID-19 One-Step RT-PCR Kit	As per pack insert	64747	Non-Listed
2.	NCVRPD-01 NCVRPD-02 NCVRPD-03	MERIL	COVID-19 IgG/IgM Rapid Test	As per pack insert	64756	Non-Listed
3.	MHLRPD-02 MHLRPD-03 MHLRPD-04 MHLRPD-05	MERISCREEN Malaria Pf/Pan Ag	One Step Test for Malaria Pf/Pan Ag	As per pack insert	52311	Non-Listed
4.	MFLRPD-03 MFLRPD-04	MERISCREEN Malaria Pf/Pv Ag	One Step Test for Malaria Pf/Pv Ag	As per pack insert	52311	Non-Listed
5.	RPWMPH-02 RPWMPH-03 RPWMPH-04	MERISCREEN Malaria Pf HRP II Ag	One Step Test for Malaria Pf HRP II Ag	As per pack insert	52336	Non-Listed
6	HVWRPD-01 HVWRPD-02	MERISCREEN HIV 1-2 WB	One Step test Rapid Test for detection of anti-HIV in Human Serun/Plasma/Whole blood	As per pack insert	48447	List A
7	RPDHBV-01	MERISCREEN HBsAg	One Step Rapid Test for HBsAg	As per pack insert	48322	List A
8	RPDHCV-01	MERISCREEN HCV	One Step Rapid Test for HCV	As per pack insert	30829	List A
9	HPCELI-01	Merilisa HCV	Enzyme immunoassay for the detection of antibodies to Hepatitis C Virus in human serum or plasma	As per pack insert	48365	List A





Certificate

No. Q5 114470 0001 Rev. 00

Holder of Certificate: **Meril Diagnostics Pvt.Ltd.**

Second Floor, D1-D3, Meril Park,
Survey No.135/2/B & 174/2, Muktanand Marg, Chala
Vapi 396191
INDIA

Certification Mark:



Scope of Certificate:

Design and Development, Manufacture and Distribution of In Vitro Diagnostic Reagents and Kits for Biochemistry, Hematology, Immunology and Molecular Biology including Point of Care Testing (POCT) Strips.

The Provision of Manufacturing and Distribution Service for Monoclonal & Polyclonal Antibody for In Vitro Diagnostic Immunology Reagents.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:Q5 114470 0001 Rev. 00

Report No.: IND2021150

Valid from: 2022-03-14

Valid until: 2025-03-13

Date, 2022-03-14

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 114470 0001 Rev. 00

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): Meril Diagnostics Pvt.Ltd.
Second Floor, D1-D3, Meril Park,, Survey No.135/2/B & 174/2,
Muktanand Marg, Chala, Vapi 396191, INDIA

see scope of certificate

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