CERTIFICATE

This is to certify that the

QUALITY MANAGEMENT SYSTEM

of

MERIL DIAGNOSTICS PVT. LTD.

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

has been assessed and found to be in conformance to the requirements of

ISO 9001:2015

This certificate is valid for the following activity:

Design and Development, Manufacture, Storage and Distribution of
In Vitro Diagnostic Biochemistry, Hematology, Immunology,
Molecular Biology and Point of Care Testing (POCT) Strips, Reagents, and Kits
Design and Development, Manufacture, Storage, Distribution,
Installation and Servicing of In Vitro Diagnostics Analyzers
The provision of Monoclonal & Polyclonal Antibody Manufacture, Storage and
Distribution for In Vitro Diagnostic Reagents for Immunology
Manufacturing and Distribution In Vitro Diagnostic Instruments (ELISA Processors,
Hematology Analyzers, Coagulation Analyzers, Electrolyte Analyzers,
Molecular Diagnostics Analyzers, Diabetic Management Analyzers and POCT Devices)

Certificate No.: IQ-22070401	
Date of initial registration	05-03-2021
Date of this certificate	03-02-2023
Certificate Expiry	04-03-2024
Recertification Due	04-03-2024

Auth Sign

To check the certification validity please visit our website- www.isplcert.com or contact at- isplcert@gmail.com

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

EGAC Accredited
QMS Certification
CAB # 012205

INDRAPRASTHA SYSTEMCERT ISPL Cert

Indraprastha SystemCert Pvt. Ltd.

Digitally signed by Matei Andrei
Date: 2023.04.26 14:32:24 EEST
Reason: MoldSign Signature
Location: Moldova

Accredited by EGAC, A Member of International Accreditation Forum

For updated information of Certification, visit- www.isplcert.com, or E Mail: info@isplcert.com, isplcert@gmail.com

201, Jaina Tower-3, A-1, Janak Puri, New Delhi-110058, India, Ph +91 9990 477 631

CERTIFICATE OF IVD NOTIFICATION

Ref. No.: BS 1175-2021

Order No.: DK 1042-2021

Belgium

Date: 07/04/2021

This is to certify that, according to the Council Directive 98/79/EC, Obelis s.a. (O.E.A.R.C.) performed all notification duties and responsibilities as the European Authorized Representative (EC REP) of:

name:	Meril Diagnostics Pvt. Ltd.
Address:	Second floor, D1-D3, Meril Park, Survey No 135/2/B, 174/2, Muktanand Marg, Chala, Vapi 396191, Gujarat, India

as stipulated and demanded by the aforementioned directive.

The Manufacturer declares that the IVD devices comply with the Directive including all essential requirements.

The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) with all the appropriate declarations according to the 98/79/EC Directive – article 10 requirements including the EC Declaration of Conformity confirming that his In-Vitro Diagnostics medical devices, as stipulated here above, are fulfilling the applicable requirements of the European Council Directive 98/79/EC

The notification of the following In-Vitro Diagnostic medical devices has been completed by Obelis s.a. (O.E.A.R.C.) on the 07/04/2021 in compliance with the European Council Directive 98/79/EC - article 10 requirements.

In-vitro diagnostic medical devices: Please See Annex A - List of Devices (5 pages, 10 Devices)

As of the 08/04/2021, and as long as the manufacturer will continue complying with the hereabove mentioned requirements* he therefore:

- Is required to affix the CE marking on these devices;

- Place these devices in the Territory of Belgium and/or the other EEA Member States (excluding territories not in alignment with Decision 2010/227/EU).

G. ELKAYAM C.E.O

Obelis s.a. - O.E.A.R.C.
Registered Address
Bld Général Wahis 53
1030 Bruxelles
Tel: +32.2.732.59.54 - Fax: +32.2.732.60.03

Mr. G. Elkayam CEO
Obelis sa

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.

* This is not a CE mark and is only provided as a template for informational purposes.

** This Certificate will be automatically void if the notification is rejected by the EU Authorities or upon termination of the EAR agreement.

Order No.: DK 1042-2021
Ref No.:BS 1175-2021

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	RPDCNA-01 RPDCNA-02	MERISCREEN COVID-19 Neutralizing Antibody Rapid Test	COVID-19 Neutralizing Antibody Rapid Test	MERISCREEN COVID-19 Neutralizing Antibody Rapid Test can detect circulating SARS-CoV-2 neutralizing antibodies that block the interaction between the receptor binding domain of the viral spike glycoprotein (RBD) with the ACE2 cell surface receptor in serum, plasma and whole blood. This test is only provided for use by clinical laboratories or to healthcare workers for point-of-care testing, and not for at home testing.	65352	Non-listed
2	CNAELI-01	MERILISA COVID-19 Neutralizing Antibody ELISA Test	COVID-19 Neutralizing Antibody ELISA Test	Merilisa COVID - 19 Neutralizing Antibody Detection Kit is a blocking enzyme-linked immunosorbent assay intended for qualitative direct detection of total neutralizing antibodies to COVID-19 in human serum and plasma.	65316	Non-listed
3	RPFHBA-01	Meril HbA1C FIA Test	HbA1C Flouro Immuno Assay	This kit is suitable for in vitro quantitative detection of the concentration of glycosylated haemoglobin (HbA1c) in human whole blood. This product is used for testing in medical and health institutions as an aid to monitor long-term glycemic status in patients with diabetes mellitus Glycosylated hemoglobin (HbA1c) is a product where glucose in the blood in combination with the hemoglobin of red blood cells. Because the degradation process is very slow, the amount of producton is no longer dissociated and is not affected by the temporary increase of blood sugar, therefore, glycosylated hemoglobin has special diagnostic value for hyperglycemia,	65322	Non-listed

				especially the large fluctuation of blood sugar. The content of glycosylated hemoglobin in the whole blood can reflect the average blood glucose level in the first 8-12 weeks at the time of detection, reflect the level of glucose metabolism in the body and the degree of diabetes control, and have positive clinical significance for the clinical diagnosis screening judgment of chronic complications and medication adjustment of diabetes mellitus.		
4	RPFMT3-01	Meril T3 FIA Test	T3 Flouro Immuno Assay	This kit is suitable for in vitro quantitative detection of the concentration of T3 (Triodothyronine) in human serum, plasma and whole blood. This product is used for testing in medical and health institutions for the auxiliary diagnosis of the assessment of thyroid function.Triodothyronine, also called T3 is a thyroid hormone affects almost every physiological process in the body including growth and development, metabolism, body temperature, and heart rate. As the largest endocrine gland in human body, the thyroid gland secretes mainly active substances including tetraiodothyronine (T4) and triodothyronine (T3), which play an extremely important role in protein synthesis, body temperature regulation, energy production and regulation The majority of T3 in serum is derived from the deiodination of peripheral tissues, and a small part of T3 is directly secreted by the thyroid gland and released into the blood Most of the T3 in serum is bound to binding proteins, of which about 90% is bound to thyroxin-binding globulin (TBG), while the rest is bound to albumin, and very little is bound to thyron-	63082	Non-listed

				binding pro-albumin (TBPA). The content of T3 in serum is 1/80 - 1/50 of that of T4, but the biological activity of T3 is 5-10 times of that of T4 T3 plays an important role in judging human physiological conditions, so it is significant to detect the content of T3 in serum.		
5	RPFMT4-01	Meril T4 FIA Test	T4 Flouro Immuno Assay	This kit is suitable for in vitro quantitative detection of the concentration of T4 (Tetraiodothyronine) in human serum, plasma and whole blood. This product is used for testing in medical and health institutions for the auxiliary diagnosis of the assessment of thyroid function. Tetraiodothyronine, also called T4, is one of the two major hormones secreted by the thyroid gland that are primarily responsible for regulation of metabolism (the other is triiodothyronine, or T3). T4 and T3 are regulated by a sensitive feedback system involving the hypothalamus and the pituitary gland. The hypothalamus releases the Thyrotropin-releasing hormone (TRH), which stimulates the pituitary to release the thyroid stimulating hormone (TSH). This causes the thyroid to release T3 and T4 and these in turn regulate the release of TRH and TSH via a feedback control mechanism. Excessive secretion of Tetralodothyronine in the body is known as hyperthyroidism, and the deficient secretion of it is called hypothyroidism. So T4 is a useful marker for the diagnosis of hypothyroidism and hyperthyroidism.	63072	Non-listed
6	RPFTSH-01	Meril TSH FIA Test	TSH Flouro Immuno Assay	This kit is suitable for in vitro quantitative detection of the concentration of TSH (Thyroid-stimulating hormone) in human serum, plasma and whole blood. This product is used for testing	54384	Non-listed

				in medical and health institutions for the auxiliary diagnosis of the assessment of thyroid function. Thyroid-stimulating hormone (TSH) is a pituitary hormone that stimulates the thyroid gland to produce thyroxine (T4), and then triiodothyronine (T3) which stimulates the metabolism of almost every tissue in the body. TSH is produced when the hypothalamus releases a substance called thyrotropin-releasing hormone (TRH). TRH then triggers the pituitary gland to release TSH. It is a glycoprotein hormone synthesized and secreted by thyrotrope cells in the anterior pituitary gland, which regulates the endocrine function of the thyroid		
7	HMTCLQ-15	Merilyzer CelQuant Edge	Hematology Analyzer	CelQuant Edge HEMATOLOGY ANALYZER is an IVD device used in clinical laboratory for hemoglobin test, blood cell count & analysis, and leukocyte three-subgroup classification count of human blood sample	35476	Non-listed
8	FAAAQ4-09, FAAAQ4-01	Merilyzer AutoQuant 400 Supremus & AutoQuant 400i	Automated Biochemistry Analyzer	AutoQuant 400 Supremus & 400i Automatic Biochemistry Analyzer, It is intended for in vitro diagnostic use and quantitative determination of clinical chemistries samples in serum, plasma, urine or cerebrospinal fluid.	56676	Non-listed
9	SAANPQ-02	Proviso	Semi Automated Nephelometry Analyzer	Proviso incorporates both turbidimetric & Nephelometric testing methods and principle of Fix-time transmission Immunoturbidimetry and fix-time immunonephelometry method. ProViso is intended to perform Complement 3 (C3), Complement 4 (C4), C-Reactive Protein (CRP), Rheumatoid Factor (RF), Microalbumin (MALB), Hemoglobin A1c (HbA1c), Immunoglobulin (IgG,IgM,IgA), Apo B, Apo A1, Antistreptolysin O (ASO), Cystatin C (CysC) of blood samples and	62413	Non-listed

				serum.		
10	FAACNQ-09	Merilyzer AutoQuant 100i	Fully Automated Biochemistry Analyzer	AutoQuant 100i Biochemistry Analyzer is intended for in vitro diagnostic use in clinical laboratories and designed for quantitative determination of clinical chemistries in serum, plasma, urine and cerebrospinal fluid samples.	56676	Non-listed

Obelis s.a.

G.ELKAYAM
C.E.O.

Obelis s.a. - O.E.A.R.C.
Registered Address :
Bld Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

Management System Certificate

Certificate No.:
248933-2017-AQ-IND-NA-PS Rev. 2.0

Initial Certification Date:
05 December 2013

Valid Until :
16 February 2022

This is to certify that the quality system of:

Meril Diagnostics Pvt. Ltd.

Second Floor, D1 – D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi-396 191, Gujarat, INDIA.

has been found to conform to the Quality Management System standard:

ISO 13485:2016/NS-EN ISO 13485:2016

This certificate is valid for the following scope:

Design, Development, Manufacture, Storage and Distribution of In-vitro diagnostic Biochemistry, Haematology, Immunology, Molecular Biology and POCT-Strips, Reagents & kits.
Design, Development, Manufacture, Storage, Distribution, Installation and Servicing of in vitro diagnostic analyzers. Purchase for resale of ELISA processors, Coagulation Analyzers and POCT devices.

End of Certificate

Place and date:
Høvik, 26 May 2021

Check Validity

NORWEGIAN ACCREDITATION
MSYS 018

For the issuing office:
DNV Product Assurance AS

Eugenie Winger Husebye
Technical Reviewer