



CERTIFICATE

This is to certify that the Quality management system for medical devices of the company

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 in compliance with the requirements of the standard

EN ISO 13485: 2016

for the following scope:

- DESIGN & DEVELOPMENT, MANUFACTURE, STORAGE AND DISTRIBUTION OF IN-VITRO DIAGNOSTIC REAGENTS & KITS: BIOCHEMISTRY, HAEMATOLOGY, IMMUNOLOGY, MOLECULAR BIOLOGY INCLUDING POINT OF CARE TESTING (POCT) STRIPS
- DESIGN & DEVELOPMENT, MANUFACTURE, STORAGE AND DISTRIBUTION OF IN-VITRO DIAGNOSTIC DEVICE: STERILE ccfDNA BLOOD PRESERVATIVE TUBE
- DESIGN, DEVELOPMENT MANUFACTURE, STORAGE, DISTRIBUTION, INSTALLATION AND SERVICING OF IN VITRO DIAGNOSTIC ANALYZERS: SEMI AUTOMATED BIOCHEMISTRY ANALYZERS, FULL AUTOMATED BIOCHEMISTRY ANALYZERS, ELISA AND CLIA PROCESSORS, HEMATOLOGY ANALYZERS, COAGULATION ANALYZERS, ELECTROLYTE ANALYZERS, MOLECULAR DIAGNOSTICS ANALYZERS, DIABETIC MANAGEMENT ANALYZERS, IMMUNOLOGY ANALYZERS AND POINT OF CARE TESTING (POCT) DEVICES
- DESIGN, MANUFACTURING AND DISTRIBUTION SERVICE FOR MONOCLONAL & POLYCLONAL ANTIBODY FOR IN VITRO DIAGNOSTIC IMMUNOLOGY REAGENTS
- PURCHASE FOR RESALE OF ELISA PROCESSORS, COAGULATION ANALYZERS, REAGENTS AND POINT OF CARE TESTING (POCT) DEVICE

Certificate no.: QMS-13-026-2024/A

Date of issue: 16/01/2025

Valid from: 16/01/2025

This revision "A" of the certificate, replace certificate QMS-13-026-2024.

On condition that the organisation will maintain an effective quality management system for medical devices, this certificate remains valid until 15/01/2028.



Ľubica Škrovanová
Head of Certification Body





CERTIFICATE

This is to certify that the Quality management system for medical devices of the company

MERIL DIAGNOSTICS PVT. LTD.

NO. 135/139, MUKTANAND MARG, CHALA, VAPI – 396 191, GUJARAT, INDIA

has been found in compliance with requirements of the standard

EN ISO 13485: 2016

for the following scope:

- DESIGN AND DEVELOPMENT, MANUFACTURE AND SALES OF IN VITRO DIAGNOSTIC BIOCHEMISTRY, HAEMATOLOGY, IMMUNOLOGY, MOLECULAR BIOLOGY INCLUDING POINT OF CARE TESTING (POCT) STRIPS, REAGENTS & KITS
- DESIGN AND DEVELOPMENT, MANUFACTURE, SALES, INSTALLATION AND SERVICING OF IN VITRO DIAGNOSTIC ANALYZERS (SEMI AUTOMATED BIOCHEMISTRY ANALYZERS, FULL AUTOMATED BIOCHEMISTRY ANALYZERS, ELISA PROCESSORS, HEMATOLOGY ANALYZERS, COAGULATION ANALYZERS, ELECTROLYTE ANALYZERS, MOLECULAR DIAGNOSTICS ANALYZERS, DIABETIC MANAGEMENT ANALYZERS AND POCT DEVICES)
- DESIGN AND DEVELOPMENT, MANUFACTURE AND SALES OF MONOCLONAL & POLYCLONAL ANTIBODY FOR IN VITRO DIAGNOSTIC IMMUNOLOGY REAGENTS
- DESIGN AND DEVELOPMENT, MANUFACTURE AND SALES OF IN-VITRO DIAGNOSTIC DEVICE: STERILE ccfdNA BLOOD PRESERVATIVE TUBE
- PROCUREMENT AND SALES OF ELISA PROCESSORS, COAGULATION ANALYZERS AND POCT DEVICES

Certificate no.: QMS-13-026-2024/B

Valid from: 22/09/2025

This revision "B" of the certificate, replace certificate QMS-13-026-2024/A issued on 16/01/2025.

On condition that the organisation will maintain an effective quality management system for medical devices, this certificate remains valid until 15/01/2028.



Lubica Škrovanová
Head of Certification Body





**Annexure 1 to the
CERTIFICATE no. QMS-13-026-2024/B**

MERIL DIAGNOSTICS PVT. LTD.

NO. 135/139, MUKTANAND MARG, CHALA, VAPI – 396 191, GUJARAT, INDIA

Branches/sites/Works/Offices covered by the certified scope:

Branches/sites/Works/Offices addresses	Activities at Site
<u>Corporate Office:</u> No. 135/139, Muktanand Marg, Chala, Vapi – 396 191, Gujarat, India.	Management, Human Resource, Marketing & Sales, Purchase
<u>Site 1:</u> Meril Campus, B. No. 8 – F2, B. No. 6 – F7, Muktanand Marg, Vapi – 396191, Gujarat, India.	Design & Development, Regulatory Affairs, Production, Quality Assurance, Quality Control, Stores & Dispatch
<u>Site 2:</u> Meril Campus, B. No. 31 – F2, Muktanand Marg, Vapi – 396 191, Gujarat, India.	Design and Development, Production, Installation, Servicing, Quality Assurance, Quality Control, Stores & Dispatch

Certificate no.: QMS-13-026-2024/B

Valid from: 22/09/2025

This revision "B" of the certificate, replace certificate QMS-13-026-2024/A issued on 16/01/2025.

On condition that the organisation will maintain an effective quality management system for medical devices, this certificate remains valid until 15/01/2028.



Lubica Škrovanová
Head of Certification Body



राष्ट्रीय जैविक संस्थान
स्वास्थ्य एवं परिवार कल्याण मंत्रालय

NATIONAL INSTITUTE OF BIOLOGICALS
Ministry of Health & Family Welfare, Government of India



A-32, Sector - 62 (Institutional Area)
NOIDA - 201309 (U.P.) - INDIA
Phones : 0120 - 2400022, 2400072
Fax : 0120 - 2403014, 2400074
e-mail : info@nib.gov.in Website : www.nib.gov.in

By Speed Post

No.N.1-63/2018-19-SRRD/IDKL/844

Dated 22/06/2018

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M/s Meril Diagnostics Pvt. Ltd.
Survey No. 135/2/B & 174/2,
Second Floor, D1-D3, Meril Park,
Muktanand Marg,
Chala, Vapi-396191, Gujarat

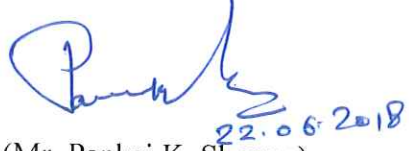
Subject: Testing of **Meriscreen HIV 1-2 WB**, Manufactured by M/s Meril Diagnostics Pvt. Ltd., Vapi, Gujarat.

Sir,

Pursuant to your License No. G/28/1438 dated 10/04/2013 and your letter dated 08/05/2018 on the under mentioned sample of **Meriscreen HIV 1-2 WB**, Manufactured by M/s Meril Diagnostics Pvt. Ltd., Vapi, Gujarat, has been tested and found to be of **Standard Quality**. The Certificate of Analysis is attached.

S.No.	Name of the Product	Batch/Lot No.	Mfg. date	Exp. date	Analytical Report No.
1.	Meriscreen HIV 1-2 WB	RD211	04/2018	03/2020	2215/IDL/2018, Dated 21/06/2018

Yours faithfully


22.06.2018
(Mr. Pankaj K. Sharma)
Scientist Grade-III



NATIONAL INSTITUTE OF BIOLOGICALS
(Ministry of Health & Family Welfare)
Government of India

F. No: N.1-63/2018-19-SRRD/IDKL

Disease Specific In-vitro Diagnostic Laboratory
CERTIFICATE OF ANALYSIS

Dated: 21.06.2018

Date of sample receipt : 10.05.2018
Start date of analysis : 12.06.2018
Sample Forwarding No. : 15691
Analytical Report No : 2215/IDL/2018
Name of the product : Meriscreen HIV1-2 WB
Name of the manufacturer : M/s Meril Diagnostics Pvt. Ltd., Gujarat
Batch / Lot No : RD211
Manufacturing date : 04.2018
Expiry date : 03.2020
Whether /Regulatory/Non Regulatory : Regulatory

S. No.	Test(s) conducted	Specifications	Results
1	Sensitivity	100%	Complies
2	Specificity	≥ 98%	

CONCLUSION: The Lot / Batch No. RD211 of product Meriscreen HIV1-2 WB as per requirement(s) of CDSCO letter No.: 29/Misc./4/2016-DC(65) dated 12.07.2017 is of Standard Quality/~~Not of Standard Quality.~~

mk jagput

Signature of the analyst
Name: Dr. Manoj Kumar
Designation: Scientist - III
Date: 21.06.2018

Dr. R. K. Sharma
21/6/2018

Signature of the Lab Head
Name: Dr. R. K. Sharma
Designation: S-III & Head
Date: 21.06.2018



3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovak Republic
Notified body No. 2265

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. 2023-IVDR/QS-002

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

SRN No.: IN-MF-000028158

Name of the Authorized representative:

Obelis s.a.; Bd., General Wahis 53, 1030, Brussels, Belgium

This EU Quality Management System Certificate issued in accordance with the Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices as amended confirms, that quality management system of in vitro diagnostic medical device:

One Step Rapid Test for Detection of Anti-HIV in Human Serum/Plasma/Whole blood

Trade Name: MERISCREEN HIV 1-2 WB

For details, see Annex I

Intended purpose: see Annex II

IVD MD class D

(detailed list is stated in the annex(es) if applicable)

meets the requirements on quality management system according to the Chapter I and III of Annex IX of the Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices as amended.

Conditions for or limitations to the validity of the certificate: **In vitro diagnostic medical device certified under the IVDR in the absence of an EURL. On sample or batch testing, NB2265 and manufacturer should follow the EURL-related provisions of Section 4.12 of Annex IX from the time that the EURL becomes operational.**

Validity of the certificate is conditional upon positive results of regular surveillance audits.

Notified body No. 2265 has performed assessment of the quality management system of the abovementioned in vitro diagnostic medical device and found that it meets the requirements stated above. The outcome of the assessment of the quality management system of the abovementioned in vitro diagnostic medical device is stated in the IVD MD Technical Documentation Assessment Report No. IVDR001_2023 from 7.9.2023, IVD MD Performance Evaluation Assessment Report No. IVDR001_2023 from 7.9.2023 and IVD MD Audit Report No. SK-0738-23 from 7.9.2023. Information on all examinations and tests performed is stated in the abovementioned reports and is available on request.

This **EU Quality Management System Certificate** applies only to the quality management system of the abovementioned in vitro diagnostic medical device. For the placing on the market of the IVD MDs which this certificate covers, the EU Technical Documentation Assessment Certificate issued in accordance with the Regulation (EU) 2017/746 on in vitro diagnostic medical devices as amended is required. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.



Valid from: **09.09.2023**
Valid until: **09.09.2028**
First issue: **09.09.2023**
Revision: **00**
History: **See Annex III**

In Bratislava, Slovakia, 09.09.2023



3EC International a.s.
Katarína Tomin Srdošová, PhD.
Director of NB2265