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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. 2023-IVDR/QS-004/A

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 Test for HBsAg
Trade Name: MERISCREEN HBsAg
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. IVDR003_2023 from 07.09.2023, IVD MD Performance Evaluation Assessment Report No. IVDR003_2023 from 07.09.2023 and IVD MD Audit Report No. SK-0738-24 from 28.06.2024. 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: **28.06.2024**
Valid until: **09.09.2028**
First issue: **09.09.2023**
Revision: **01**
History: **See Annex III**

In Bratislava, Slovakia, 28.06.2024

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

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

ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2023-IVDR/QS-004/A

issued for 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

List of in vitro diagnostic medical devices covered by the EU Quality Management System Certificate:

Type No.	Trade Name	Other Trade Names
RPDHBV-01, 50 Tests	MERISCREEN HBsAg	-
RPDHBV-03, 30 Tests	MERISCREEN HBsAg	-

Notified body
3EC international
NB 2265
NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 28.06.2024
Valid until 09.09.2028

ANNEX II TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2023-IVDR/QS-004/A

issued for 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

Intended purpose of in vitro diagnostic medical devices covered by the EU Quality Management System Certificate:

MERISCREEN HBsAg is a qualitative, In-Vitro diagnostic immuno-chromatography assay based on lateral flow technology for the detection of Hepatitis-B surface antigen (HBsAg), a marker of hepatitis-B virus in human serum or plasma. This kit is designed for screening & diagnosis of Hepatitis B virus infection and intended to be used by healthcare professionals as an aid to diagnosis. The assay is manual and does not require additional instruments.

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Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 28.06.2024
Valid until 09.09.2028

ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2023-IVDR/QS-004/A

issued for 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

Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application for Conformity Assessment of IVD MD number	Description
00	2023-IVDR/QS-004	09.09.2023	IVDR003_2023	Initial issue
01	2023-IVDR/QS-004/A	28.06.2024	IVDR003_2023/A	Added product code: RPDHBV-03, 30 Tests

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 28.06.2024
Valid until 09.09.2028

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

EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE

No. 2023-IVDR/TD-004/A

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 Technical Documentation Assessment 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 technical documentation of the in vitro diagnostic medical device:

One Step Test for HBsAg
Trade Name: MERISCREEN HBsAg
For details, see Annex I
Intended purpose: see Annex II
IVD MD class D
Basic UDI-DI: 8905459MHBSAGRTG4
(detailed list is stated in the annex(es) if applicable)

meets the requirements of technical documentation assessment according to the Chapter II 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 technical documentation assessment of the abovementioned in vitro diagnostic medical device and found that it meets the requirements stated above. The outcome of the technical documentation assessment of the abovementioned in vitro diagnostic medical device is stated in the IVD MD Technical Documentation Assessment Report No. IVDR003_2023 from 07.09.2023, IVD MD Performance Evaluation Assessment Report No. IVDR003_2023 from 07.09.2023 and IVD MD Audit Report No. SK-0738-24 from 28.06.2024. Information on all examinations and tests performed is stated in the abovementioned reports and is available on request.

This **EU Technical Documentation Assessment Certificate** applies only to the abovementioned in vitro diagnostic medical device. For the placing on the market of the IVD MDs which this certificate covers, the EU Quality Management System 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: **28.06.2024**
Valid until: **09.09.2028**
First issue: **09.09.2023**
Revision: **01**
History: **See Annex III**

In Bratislava, Slovakia, 28.06.2024

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

ANNEX I TO EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE No. 2023-IVDR/TD-004/A

issued for 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

List of in vitro diagnostic medical devices covered by the EU Technical Documentation Assessment Certificate:

Type No.	Trade Name	Other Trade Names
RPDHBV-01, 50 Tests	MERISCREEN HBsAg	-
RPDHBV-03, 30 Tests	MERISCREEN HBsAg	-

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In Bratislava, Slovakia, 28.06.2024
Valid until 09.09.2028

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ANNEX II TO EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE No. 2023-IVDR/TD-004/A

issued for 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

Intended purpose of in vitro diagnostic medical devices covered by the EU Technical Documentation Assessment Certificate:

MERISCREEN HBsAg is a qualitative, In-Vitro diagnostic immuno-chromatography assay based on lateral flow technology for the detection of Hepatitis-B surface antigen (HBsAg), a marker of hepatitis-B virus in human serum or plasma. This kit is designed for screening & diagnosis of Hepatitis B virus infection and intended to be used by healthcare professionals as an aid to diagnosis. The assay is manual and does not require additional instruments.

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Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 28.06.2024
Valid until 09.09.2028

ANNEX III TO EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE No. 2023-IVDR/TD-004/A

issued for 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

Certificate history:

Revision	EU TD Assessment Certificate reference	Date of issue	Application for Conformity Assessment of IVD MD number	Description
00	2023-IVDR/TD-004	09.09.2023	IVDR003_2023	Initial issue
01	2023-IVDR/TD-004/A	28.06.2024	IVDR003_2023/A	Added product code: RPDHBV-03, 30 Tests

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

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In Bratislava, Slovakia, 28.06.2024
Valid until 09.09.2028