Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 1 din 20.10.2023

Solicitantul SRL Biosistem mld, cu sediul str. Albișoara 16/1 of.7, or. Chișinău
(adresa)
Tel./Fax: .+373-22-808517, +373-22-808719, fax +373-22-808519, e-mail biosistem.mld@gmail.com; info@biosistem-mld.com, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

- One Step Rapid Test Kit for detection of Anti-HIV in Human Serum/Plasma/Whole Blood

Se anexează următoarele acte:
Declaraţie pe proprie răspundere
Declaratie de conformitate
Scrisoare de imputernicire

Data 20.10.2023 Semnătura _____

Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Digitally signed by Poiata Vitalie
Date: 2023.10.20 17:05:09 EEST
Reason: MoldSign Signature
Location: Moldova

Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: SRL Biosistem mld, cu sediul str. Albișoara 16/1 of.7, or. Chișinău, declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

- One Step Rapid Test Kit for detection of Anti-HIV in Human Serum/Plasma/Whole Blood

Sunt autentice și corespund realității.

Administrator: Poiata Vitalie *Semnătura* _____

Data 20.10.2023

MDPL/LOA/040/2023

October 20,2023

MANUFACTURERS AUTHORIZATION

Biosistem-mld SRL
Albisoara 16/1 ap.7
Chisinau, R. Moldova

To: Whomever it may concern

We, Meril Diagnostics Pvt. Ltd., manufacturer of medical products with principal place of business at **Survey No. 135/139, Bilakhia House, Muktanand Marg, Chala, Vapi-396 191, Gujarat, India** hereby confirm that **Biosistem mld SRL** with business office at Albisoara 16/1 ap.7, Chisinau, Republic of Moldova, is authorized by the company, to carry out the registration of products manufactured by Meril Diagnostics Pvt. Ltd.

This authorization is valid for 1 year from the date of issuance and automatically renewable if no termination letter issued.

For, Meril Diagnostics Private Limited

MERIL DIAGNOSTICS PRIVATE LIMITED
CHALA
VAPI

Date: 09-10-2023

DECLARATION OF CONFORMITY

I, Mr. Pratik Vasani of Meril Diagnostics Pvt. Ltd, hereby declare that the below mentioned medical device-

(i) complies with all the requirements under the Act;

(ii) has been classified according to the classification rules as specified in First Schedule on Rules of Classification of Medical Device; and

(iii) conforms to requirements specified in APPENDIX 1 of Third Schedule on Essential Principles for Safety and Performance of Medical Devices under Medical Devices Regulations 2012.

(A) Particulars of medical device

Generic name : One Step Rapid Test Kit for detection of Anti-HIV in Human Serum/Plasma/Whole Blood
Specified name: MERISCREEN HIV 1-2 WB
Brand/model: MERISCREEN HIV 1-2 WB
Country of origin: India
Manufacturer: Meril Diagnostics Pvt. Ltd.
Manufacturing site: Second Floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi-396191, India.
Risk-based classification: Class D
Classification rule: Rule-1 first indent as per Annex VIII of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices
GMDN code: 48447
Medical device registration number or any approval code:
Certificate number: 2023-IVDR/TD-002 (EU Technical Documentation Certificate)
: 2023-IVDR/QS-002 (EU Quality Management System Certificate)
Issuance date : 09-09-2023
Expiry date : 09-09-2028

(B) Quality Management System certificate ("QMS")

Conformity Assessment Body issuing the certificate: TUV SUD Product Service GmbH
Certificate number: Q5 1144700002 Rev.00
Issuance date : 2022-07-13
Expiry date : 2025-03-13

List of Standards		
Sr. No.	**Standard Ref. No.**	**Title Description**
1.	EN 13975:2003	Sampling procedures used for acceptance testing of in vitro diagnostic medical devices - Statistical aspects
2.	EN 13641:2002	Elimination Or Reduction Of Risk Of Infection Related To In Vitro Diagnostic Reagents
3.	EN 13612: 2002	Performance evaluation of in vitro diagnostic medical devices
4.	EN 14136:2004	Use of external quality assessment schemes in the assessment of the performance of in vitro diagnostic examination procedures
5.	BS EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
6.	EN ISO 13485:2016	Medical Devices – Quality Management System Requirements for Regulatory Purpose (ISO 13485:2016)
7.	ISO 14971:2019 (E)	Medical devices - Application of risk management to medical devices
8.	BS EN ISO 14971:2019+A11:2021	In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 1: Terms, definitions and general requirements (ISO 18113- 1:2009)
9.	EN ISO 18113- 2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113- 2:2009)
10.	EN ISO 18113- 2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113- 2:2009)
11.	EN ISO 15193:2009	In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for content and presentation of reference measurement procedures (ISO 15193:2009)
12.	EN ISO 15194:2009	In vitro diagnostic medical device – Measurement of quantities in samples of biological origin – Requirements for certified reference materials and the content of supporting documentation (ISO 15194:2009)
13.	EN ISO 15223- 1:2021	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
14.	EN ISO 17511:2021	In vitro diagnostic medical devices — Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples
15.	EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability on in vitro diagnostic reagents (ISO 23640:2011)
16.	ISO 9001:2015	Quality Management System Requirement
17.	EN ISO 14644- 1:2015 (E)	Clean rooms and associated controlled environments Part 1: Classification of Air Cleanliness
18.	EN ISO 14644- 2:2015 (E)	Clean rooms and associated controlled environments Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
19.	BS EN ISO 14644-3:2019	Clean rooms and associated controlled environments Part 3: Test Methods
20.	ISO 14644-4:2001	Clean rooms and associated controlled environments -- Part 4: Design, construction and start-up

21.	EN 62366-1:2015	Medical Devices - Part 1: Application of Usability Engineering to Medical Devices
22.	EN ISO 20916:2019	In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice
23.	Schedule M – IV	Good Manufacturing Practices & Requirements of Premises, Plant & Equipment for IVD Reagents & Kits
24.	EU IVDR 2017/746	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices and Repealing Directive 98/79/EC and Commission Decision 2010/227/EU
25.	EU 2022/1107	COMMISSION IMPLEMENTING REGULATION (EU) 2022/1107 of 4 July 2022 laying down common specifications for certain class D in vitro diagnostic medical devices in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council

I am fully responsible with all the information provided in this declaration. This declaration of conformity is valid from 07-10-2023.

I fully understand and acknowledge that it is an offence under Section 76 of the Medical Device Act 2012 [Act 737] to make, sign or furnish any declaration, certificate or other document which is untrue, inaccurate or misleading.

Authorised Signature: Official Stamp :

Meril Diagnostics Pvt. Ltd. Vapi

_____

Name: Pratik Vasani

Designation: AGM- Regulatory Affairs

Date: 09-10-2023

Note: MDA Guidelines for Declaration of Conformity (DOC)

The signatory

The DoC shall be signed by the person as detailed out below:

i) For local manufacturer, the signatory is the top management or the person responsible as declared in 6 (h); and

ii) For foreign manufacturer, the signatory is any person in the top management category of the foreign manufacturer.

Top Management is the person responsible having the overall control and have the authority to make decision. Depending on the organization structure of the establishment. Person responsible includes Proprietor, President, Vice President, Director, Chief Executive Officer (CEO), Managing Director or General Manager.

Attachment 1

No.	Name of Medical Device	Identifier	Brief Description of Item
1.	MERISCREEN HIV 1-2 WB	HVWRPD-01 HVWRPD-02 HVWRPD-06 HVWRPD-07 HVWRPD-08	MERISCREEN HIV 1-2 WB Test is a single use, qualitative, screening, in-vitro diagnostic immunochromatography assay and used for detection of antibodies (IgG, IgA and IgM) specific to HIV-1 and HIV-2 in human fingerstick whole blood, venous whole blood, serum or plasma specimens. The test is intended for healthcare professionals (either in laboratory or in point-of care setting) to aid in the diagnosis of infection with HIV-1 and HIV-2 and for the diagnosis of HIV infection in symptomatic, asymptomatic and persons at risk of HIV infections. It is not intended for testing children below 2 years. The assay is manual and does not require additional instrument.

End of Attachment 1

ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2023-IVDR/QS-002

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
HVWRPD-01, 30 Tests	MERISCREEN HIV 1-2 WB	-
HVWRPD-02, 40 Tests	MERISCREEN HIV 1-2 WB	-
HVWRPD-06, 50 Tests	MERISCREEN HIV 1-2 WB	-
HVWRPD-07, 10 Tests	MERISCREEN HIV 1-2 WB	-
HVWRPD-08, 100 Tests	MERISCREEN HIV 1-2 WB	-

Notified body · 3EC International · NB 2265 · NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 09.09.2023
Valid until 09.09.2028

ANNEX II TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2023-IVDR/QS-002

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 HIV 1-2 WB is a single use, qualitative, screening, in-vitro diagnostic immunochromatography assay and used for detection of antibodies (IgG, IgA and IgM) specific to HIV-1 and HIV-2 in human fingerstick whole blood, venous whole blood, serum or plasma specimens. The test is intended for healthcare professionals (either in laboratory or in point-of-care setting) to aid in the diagnosis of infection with HIV-1 and HIV-2 and for the diagnosis of HIV infection in symptomatic, asymptomatic and persons at risk of HIV infections. It is not intended for testing children below 2 years. The assay is manual and does not require additional instrument.

Notified body · 3EC international · NB 2265 · NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 09.09.2023
Valid until 09.09.2028

ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2023-IVDR/QS-002

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-002	09.09.2023	IVDR001_2023	Initial issue

Notified body · 3EC international · NB 2265 · NOTIFIKOVANÁ OSOBA

Katarina Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 09.09.2023
Valid until 09.09.2028

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

Notified body · 3EC International · NB 2265 · NOTIFIKOVANÁ OSOBA

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

ANNEX I TO EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE No. 2023-IVDR/TD-002

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
HVWRPD-01, 30 Tests	MERISCREEN HIV 1-2 WB	-
HVWRPD-02, 40 Tests	MERISCREEN HIV 1-2 WB	-
HVWRPD-06, 50 Tests	MERISCREEN HIV 1-2 WB	-
HVWRPD-07, 10 Tests	MERISCREEN HIV 1-2 WB	-
HVWRPD-08, 100 Tests	MERISCREEN HIV 1-2 WB	-

Notified body · 3EC international · NB 2265 · NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 09.09.2023
Valid until 09.09.2028

ANNEX II TO EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE No. 2023-IVDR/TD-002

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 HIV 1-2 WB is a single use, qualitative, screening, in-vitro diagnostic immunochromatography assay and used for detection of antibodies (IgG, IgA and IgM) specific to HIV-1 and HIV-2 in human fingerstick whole blood, venous whole blood, serum or plasma specimens. The test is intended for healthcare professionals (either in laboratory or in point-of-care setting) to aid in the diagnosis of infection with HIV-1 and HIV-2 and for the diagnosis of HIV infection in symptomatic, asymptomatic and persons at risk of HIV infections. It is not intended for testing children below 2 years. The assay is manual and does not require additional instrument.

Notified body
3EC international
NB 2265
NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 09.09.2023
Valid until 09.09.2028

ANNEX III TO EU TECHNICAL DOCUMENTATION
ASSESSMENT CERTIFICATE No. 2023-IVDR/TD-002

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-002	09.09.2023	IVDR001_2023	Initial issue

Notified body
3EC International
NB 2265
NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 09.09.2023
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-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 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 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
Basic UDI-DI: 8905459MHVWRPDJX
(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. 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 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: **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

Notified body · 3EC International · NB 2265 · NOTIFIKOVANÁ OSOBA

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