EU DECLARATION OF CONFORMITY (DoC)

1. IDENTIFICATION OF COMPANY

Manufacturer's Name	:	MERIL DIAGNOSTICS PVT. LTD.

2. SRN- SINGLE REGISTRATION NUMBER

Manufacturer's SRN No.	:	IN-MF-000028158
EU Authorized Representative's SRN No.	:	BE-AR-000000106

3. ADDRESS AND CONTACT DETAILS

Manufacture	:	Second Floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi – 396191, Gujarat, India.
European Authorized Representative	:	Obelis S.A., Bd., General Wahis 53, 1030, Brussels, Belgium, Tel: +32.2.732.5954, Fax: +32.2.732.6003, E-mail: mail@obelis.net

4. PRODUCT IDENTIFICATION

Name	:	HIVFIND Whole Blood HIV 1/2 antibody detection self test
Trade Name	:	HIVFIND
Batch No.	:	
Quantity	:	
Manufacturing Date	:	
Expiry Date	:	
Batch Release Date	:	
EMDN/GMDN code	:	W0105090302/ 65848
DoC No.	:	CE-DOC/IM/CLD/022, Rev. No.: 01
Issue Date	:	04/06/2024

5. INTENDED PURPOSE

HIVFIND Whole Blood HIV 1/2 antibody detection self test is a qualitative, screening, In-vitro diagnostic immunochromatography assay for the detection of antibodies specific to HIV (HIV1 & HIV-2) in whole blood. The test is intended to use by individuals in a private setting as a self test to aid in the diagnosis of HIV infection with self collected finger prick blood sample.

6. Basic UDI-DI : 890549HIVWBSFEL

7. PRODUCT CODES : HIVWBS-01, HIVWBS-02, HIVWBS-03, HIVWBS-04

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8. RISK CLASS : Class D, Rule 1, Second Indent

HIVFIND Whole Blood HIV 1/2 antibody detection self test is classified as Class D, Rule 1 second 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 and Repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

Devices intended to be used for the following purposes are classified as class D and comes under Rule 1 second indent: — Devices intended to be used for the detection of the presence of, or exposure to, a transmissible agent that causes a life-threatening disease with a high or suspected high risk of propagation.

HIVFIND Whole Blood HIV 1/2 antibody detection self test is intended for antibodies specific to HIV (HIV1 & HIV-2) in fingerprick whole blood. Thus, device is intended for detection of antibodies specific to HIV (HIV1 & HIV-2) in human blood. HIV1 & HIV2 virus is transmissible agent that causes HIV infection in human which is considered as life-threatening disease. Transmission of HIV infection is mainly by exposure to certain infected body fluids e.g., blood and blood components, genital secretions etc. and by transplacental route that can be a high risk of propagation of HIV infection in population where monitoring is critical in the process of patient management.

9. NOTIFIED BODY

Name	:	3EC International a.s.
Address	:	Hranicna 18, 821 05 Bratislava, Slovak Republic
Notified Body Identification Number	:	2265
Description of the Conformity Assessment procedure	:	Annex IX Conformity assessment based on a quality management system and assessment of the technical documentation
The CE Certificate number	:	EU Technical Documentation Assessment Certificate No.: 2024-IVDR/TD-003 EU Quality Management System Certificate No.: 2024-IVDR/QS-003
Applicable Guidelines/Standards/Commo Specifications (CS)	:	EU IVDR 2017/746, EU 2022/1107, EN 13975:2003, EN 13641:2002, EN 13612:2002, EN 14136:2004, BS EN 62366-1:2015, EN ISO 13485:2016, EN ISO 13485:2016+A11:2021, ISO 14971:2019,BS EN ISO 14971:2019+A11:2021, EN ISO 18113-1:2011, EN ISO 18113-2:2011, BS EN ISO 18113-4:2011, EN ISO 15193:2009, EN ISO 15194:2009, EN ISO 17511:2021, EN ISO 23640:2015, EN ISO 15223-1:2021, ISO 14644-1: 2015, ISO 14644-2: 2015, BS EN ISO 14644-3: 2019, ISO 14644-4: 2001, EN ISO 20916:2019, MDCG 2022-2, MDCG 2020-7, MDCG 2020-8, MDCG 2022-9, MDCG

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2018-1, MDCG 2021-19, MDCG 2020-16

10. STATEMENTS

We declare that our products as listed above in section 4.0, comply with the requirements to REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017, Annex IV and EU declaration of conformity is issued under the sole responsibility of Meril Diagnostics Pvt. Ltd.

1. The device that is covered by this declaration is in conformity with Regulation (EU) 2017/746 and if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.
2. Company undertakes to manufacture the products as per National/ International Standards and following quality management system as per EN ISO 13485:2016/ ISO 13485:2016/DIN EN ISO 13485:2016.
3. Company authorizes the notified body to carry out necessary audits and agrees to supply the required information & data/documents.
4. Company agrees to make available all relevant Documents & Data of the products to the National and Competent Authority for a period ending 10 (ten) years for IVDs after the last device covered by the EU declaration of conformity has been placed on the market.
5. Company &/or its authorized representative shall fulfill the obligations imposed by Annex IX of REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 & shall ensure & declare that the Company's Products shall meet all provisions of the regulation as applicable.
6. Company undertakes to keep up to date a systematic procedure to review experience gained during post production phase and to implement appropriate means to apply any necessary corrective action taking account of the nature & risk in relation to the product.
7. Company undertakes to notify immediately any malfunction /deterioration of the performance of the device to the appropriate authority and shall recall such devices already placed in the market.
8. Company shall fulfill the obligations imposed by Annex I of REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 and shall ensure and declare that the Company's Products shall meet all the provisions of the regulation as applicable.

11. APPROVAL

For Meril Diagnostics Pvt. Ltd.

Location	:	Vapi, Gujarat, INDIA
Name	:	Mr. Narendra Patel
Designation	:	General Manager, RA & QA
Signature	:	

MERIL DIAGNOSTICS PRIVATE LIMITED ★ CHALA, VAPI

Date	:	

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12. AMENDMENT HISTORY:

Revision No.	Date	Amendment Description
00	12/09/2023	Initial Issue
01	As on Issue Date	The EU Technical Documentation Assessment Certificate No. and EU Quality Management System Certificate No. are updated.

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