Meril
Diagnostics

# EU DECLARATION OF CONFORMITY (DoC)

## 1. IDENTIFICATION OF COMPANY

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| **Manufacturer's Name** | : | MERIL DIAGNOSTICS PVT. LTD. |

## 2. SRN- SINGLE REGISTRATION NUMBER

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

## 3. ADDRESS AND CONTACT DETAILS

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| **Company's registered office address** | : | Meril Diagnostics Private Limited, No. 135/139, Bilakhia House, Muktanand Marg, Chala. Vapi, Valsad, Gujarat (India) – 396191 |
| **Manufacturing site address** | : | Meril Diagnostics Pvt. Ltd., Meril Campus, B. No. 8- F2, B. No. 6-F7, Muktanand Marg, 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™ Oral fluid HIV 1/2 Antibody Detection Self Test |
| **Trade Name** | : | HIVFIND™ |
| **Batch No.** | : | |
| **Quantity** | : | |
| **Manufacturing Date** | : | |
| **Expiry Date** | : | |
| **Batch Release Date** | : | |
| **EMDN code** | : | W0105090302 |
| **DoC No.** | : | CE-DOC/IM/CLD/023, Rev. No.: 03 |
| **Issue Date** | : | 02/06/2026 |

## 5. INTENDED PURPOSE

HIVFINDTM Oral Fluid HIV 1/2 Antibody Detection Self Test is a qualitative screening *in-vitro* diagnostic immunochromatography assay for the detection of antibodies specific to HIV (HIV-I & HIV in Oral Fluid. the test is intended to be used by individuals in private setting as a self test to aid in the diagnosis of HIV infection with self collected Oral Fluid.

Meril
Diagnostics

6. **Basic UDI-DI** : 890549HIVOSF9V

7. **PRODUCT CODES** : HIVSST-01, HIVSST-02, HIVSST-03, HIVSST-04

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

HIVFIND™ Oral Fluid 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™ Oral Fluid HIV 1/2 antibody detection self test is a qualitative screening in-vitro diagnostic immunochromatography assay for the detection of antibodies specific to HIV (HIV-1 & HIV-2) in Oral Fluid. The test is intended to be used by individuals in a private setting as a self-test to aid in the diagnosis of HIV infection with self-collected oral fluid. 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**

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| **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.: 2025-IVDR/TD-001<br>EU Quality Management System Certificate No.: 2025-IVDR/QS-001 |
| **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, EN 62366-1:2015, EN ISO 13485:2016, EN ISO 14971:2019,BS EN ISO 14971:2019+A11:2021, EN ISO 18113-1: 2024, EN ISO 18113-2 : 2024, EN ISO 18113-4:2024, EN ISO 15193:2009, |

Meril

Diagnostics

EN ISO 15194:2009, EN ISO 17511:2021, EN ISO 23640:2015, EN ISO 15223-1:2021/Amd. 1:2025, EN ISO 14644-1: 2015 (E), EN ISO 14644-2: 2015 (E), BS EN ISO 14644-3: 2019 (E), EN ISO 14644-4: 2022 (E), EN ISO 20916:2019

## 10. STATEMENTS

We declare that our products as listed above in section 4.0, comply with the requirements of 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.**

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| **Location** | : | Vapi, Gujarat, INDIA |
| **Name** | : | Mr. Ram Kanoje |
| **Designation** | : | Head – QA |
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MERIL DIAGNOSTICS PVT. LTD. VAPI

**Date** :

## 12. AMENDMENT HISTORY:

| Revision No. | Date | Amendment Description |
|---|---|---|
| 00 | 14/10/2024 | Initial Issue |
| 01 | 30/04/2025 | Applicable Guidelines/Standards/ Common Specifications (CS) are updated. |
| 02 | 22/05/2025 | The CE Certificate number is updated |
| 03 | 02/06/2026 | Company's registered office address and manufacturing site address has been updated |