



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

## EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE No. 2025-IVDR/TD-001

### 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 and address of the Authorized representative:

Obelis s.a.; Bd., General Wahis 53, 1030, Brussels, Belgium  
SRN No.: BE-AR-000000106

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:

### HIVFIND™ Oral Fluid HIV 1/2 Antibody Detection Self Test

(for detailed list refer to Annex I)

Intended purpose: Annex II

IVD MD class D

Basic UDI-DI: 8905459HIVOSF9V

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.

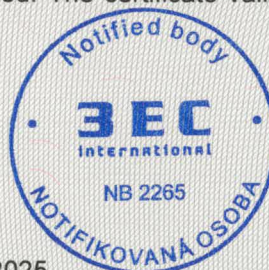
Notified body No. 2265 has performed technical documentation assessment of the above mentioned in vitro diagnostic medical device and found that it meets the requirements stated above. The outcome of the technical documentation assessment of the above mentioned in vitro diagnostic medical device is stated in the IVD MD Technical Documentation Assessment Report No. IVDR013\_2023 from 12.12.2024, IVD MD Performance Evaluation Assessment Report No. IVDR013\_2023 from 16.01.2025 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 above mentioned 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: **20.03.2025**  
Valid until: **09.09.2028**  
First issue: **20.03.2025**  
Revision: **00**  
History: **Annex III**

In Bratislava, Slovakia, 20.03.2025



3EC International a. s.  
Katarina Tomín Srdošová, PhD.  
Director of NB 2265



## ANNEX I TO EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE No. 2025-IVDR/TD-001

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:

IVD medical device	Trade Name	Product code
HIVFIND™ Oral Fluid HIV 1/2 Antibody Detection Self Test	HIVFIND™	HIVSST-01
		HIVSST-02
		HIVSST-03
		HIVSST-04

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In Bratislava, Slovakia, 20.03.2025  
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## ANNEX II TO EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE No. 2025-IVDR/TD-001

issued for the company

### Meril Diagnostics Pvt. Ltd.

Second Floor, D1 - D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala,  
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#### Intended purpose of in vitro diagnostic medical devices covered by the EU Technical Documentation Assessment Certificate:

The HIVFIND™ Oral Fluid HIV 1/2 Antibody Detection Self Test is a qualitative, screening rapid assay test that detects antibodies specific to HIV (HIV-1 and HIV-2) in oral fluid. This test is designed for lay user in a private setting to aid in the diagnosis of HIV infection using self-collected oral fluid specimens. It is not automated test.

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# ANNEX III TO EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE No. 2025-IVDR/TD-001

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	2025-IVDR/TD-001	20.03.2025	IVDR013_2023	Initially granted certification

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