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	:	**Address of registered place of business:** MERIL DIAGNOSTICS PRIVATE LIMITED, No. 135/139, Bilakhia House, Muktanand Marg, Chala, Vapi-396191, Gujarat, INDIA **Address of Manufacturing Site:** 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
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

Medical device group	:	Rapid self test
In Vitro Medical device Name	:	Early Pregnancy Test
Trade Name	:	EzeeFind™
Batch No.	:	
Quantity	:	
Manufacturing Date	:	
Expiry Date	:	
Batch Release Date	:	
EMDN/GMDN code	:	W0102160302
DoC No.	:	CE-DOC/IM/CLB/008, Rev. No.: 01
Issue Date	:	05/11/2024

5. INTENDED PURPOSE

The EzeeFind™ early pregnancy test is a qualitative screening test intended for self-testing, by detecting of human chorionic gonadotropin (hCG) in urine if its concentration is equal or

higher than 10 mIU/ml. The product is intended for use by lay persons to determine the state of pregnancy.

6. Basic UDI-DI : 8905459HCGRTSF8Q

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

8. RISK CLASS : Class B, Rule 4a,

EzeeFind™ Early Pregnancy Test is classified as Class B, Rule 4a 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.

Justification:

Rule 4a applies to devices intended for self-testing. Devices intended to be used for the following purposes are classified as Class B & comes under rule 4a: – Devices intended for self-testing are classified as class C, except for devices for the detection of pregnancy, for fertility testing and for determining cholesterol level, and devices for the detection of glucose, erythrocytes, leucocytes and bacteria in urine, which are classified as class B.

EzeeFind™ Early Pregnancy Test is a pregnancy self-test that detects the presence of hCG hormone in human urine, one that determines whether you're pregnant. Thus, EzeeFind™ Early Pregnancy Test is intended for detection of hCG in human urine that determines the pregnancy status of women by self tester at home setting.

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.: EU Quality Management System Certificate No.:
Applicable Guidelines/Standards/Commo Specifications (CS)	:	EU IVDR 2017/746, EN 13975:2003, EN 13641:2002, EN 13612:2002, EN 14136:2004, EN 62366-1:2015, EN ISO 13485:2016, EN ISO 13485:2016+A11:2021, ISO 14971:2019, 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, 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, EN ISO 14644-3: 2019, ISO 14644-4: 2001, EN ISO 20916:2019.\

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	:	Senior General Manager, RA & QA
Signature	:	
Date	:	

MERIL DIAGNOSTICS PRIVATE LIMITED ★ CHALA, VAPI

12. Amendment History

Table 1: Amendment History

Sr. No.	Revision No.	Date	Amendment Description
1	00	17/04/2024	Initial Issue
2	01	23/09/2024	Name and Trade name are corrected. The applicable standards /guidelines/common specifications is updated. The Provision of CE mark is amended in the DOC.
3	02	As on approval page	The Intended Purpose is updated as per the term used in IVDR.