



E.A.R. - CERTIFICATE

(Article 11.2 of the Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices)

Reference No.:

Date:

Order No.:

Expiration Date:

Manufacturer:

Facilities:

Product Category(ies):

Model(s):

The European Authorized Representative Obelis s.a. declares that the aforementioned manufacturer has fulfilled the requirement of appointing a European Authorized Representative* in accordance with article 11.2 of the Regulation (EU) 2017/746 and to the terms and conditions set out in the agreement entered into force on **

Obelis s.a. - O.E.A.R.C.

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Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.).
Obelis s.a. is ISO 9001 : 2015 and ISO 13485 : 2016 certified.

*This certificate is not a confirmation of product notification nor an approval to place products on the market.

**This certificate will become void automatically upon termination of the EAR agreement

ANNEX to IVDR Certificates

Manufacturer: Meril Diagnostics Pvt Ltd

Country: India

#	Name of device	Intended use	Class and Rule under MDR/IVDR	EMDN Code	GMDN Code	Basic UDI-DI	Mandated (Y/N)	Mandate starting date	Mandated Vigilance (Y/N)
1	Merilisa HCV	Merilisa HCV is an in-vitro diagnostics Enzyme immunoassay for the qualitative determination of antibodies to Hepatitis C Virus in human serum or plasma. Merilisa HCV test is to be used for screening and as an aid in diagnosis of Hepatitis caused by infection of Hepatitis C virus in symptomatic patients.	Class D, Rule 1	W01050 203	n/a	8905459M HCVLIA4	Y	30/03/2026	N
2	HIVFIND™ Oral fluid HIV 1/2 Antibody Detection Self Test	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.	Class D, Rule 1	W01050 90302	n/a	8905459HI VOSF9V	Y	30/03/2026	N

Obelis s.a.

Date:

Stamp

[History log](#)

Version number	Version Date	Order Form number	Reference Number	Action
V1	14/04/2026	EU MA 0631-2025	CS 0210-2026	First issuance