Meril
Diagnostics

DECLARATION OF CONFORMITY

Manufacturer's Name:	**MERIL DIAGNOSTICS PVT. LTD.**
Manufacturer's Address:	Second Floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi – 396191, Gujarat, India.
Product Name:	Merilisa HCV
Product Details:	Control No. CE-DOC/IM/GRA/003/ Rev.03/18.08.2021 GMDN Code: 48365 Ref. No.: HPCELI-01

Conforms to the applicable national and international standards.

1. We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All the supporting documentations are retained under the premises of the manufacturer.
2. Company undertakes to manufacture the products as per National/ International Standards and following quality management system as per EN ISO 13485:2012/ ISO 13485:2016 & ISO 9001:2008.
3. Company authorizes the notified body to carry out necessary inspection and agrees to supply the required information & data/documents from time to time.
4. Company agrees to make available all relevant Documents & Data of the products to the National and competent Authority for a period ending 05 years for IVD reagents and kits after the last product has been manufactured.
5. Company &/or his authorized representative shall fulfill the obligations imposed by Annex I of Directive 98/79/EC as amended & ensures & declares that the Company's Products shall meet all provision of the directive 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

General applicable directives:	DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices
List of Standard Applied:	EN 13975:2003, EN 13641:2002, EN 13612 : 2002, EN 14136:2004, BS EN 1041:2008+A1:2013, BS EN 62366-1:2015, EN ISO 13485:2016, ISO 14971:2019, EN ISO 18113-1: 2011, EN ISO 18113-2 : 2011, EN ISO 15193:2009, EN ISO 15194:2009, EN ISO 17511:2003, 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
Conformity Assessment Route:	Annex: IV of Directive 98/79/EC on In vitro Diagnostic Medical Devices
Device Classification:	List A device as per Annex II of Directive 98/79/EC
European Authorized Representative:	Obelis s.a. Bd., General Wahis 53, 1030, Brussels, Belgium. T +32.2.732.5954 F +32.2.732.6003 E mail@obelis.net
CE Certificate No.:	1434-IVDD-108/2018
CE Certificate Valid till:	12-07-2023
Notifying Body:	Polish Centre for Testing and Certification (CE1434)
Signature:	
Name:	Mr. Ram Kanoje
Designation:	Head, Quality Assurance
Date/Location:	**Date**: _____ **Location**: Vapi, Gujarat, INDIA

MERIL DIAGNOSTICS PVT. LTD. VAPI

CE 1434

Digitally signed by Jighili Tatiana
Date: 2023.12.15 12:19:17 EET
Reason: MoldSign Signature
Location: Moldova