

# Product label

## LiverPRO IVD medical software

Milos Ilic (MR, Regulatory consultant) milos@evido.health

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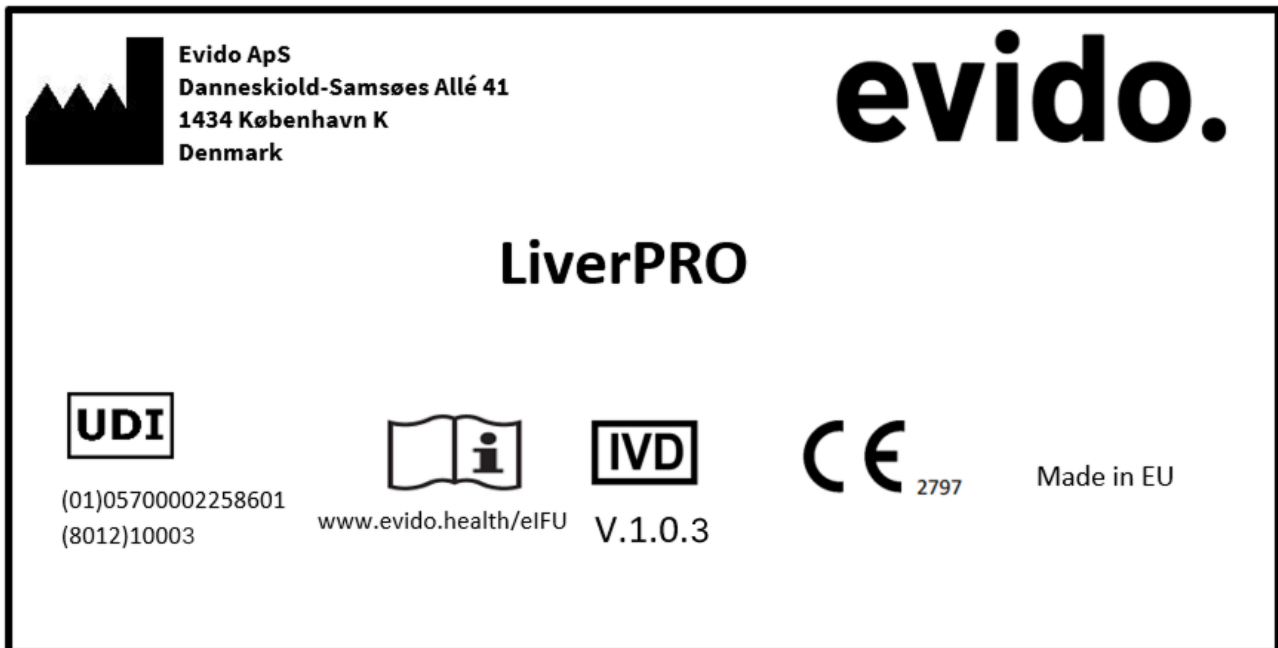
## 1 Product label

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IVD Medical Software

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LiverPRO



### 1.1 Regulatory basis

Document ID	Document Title
IVDR (EU) 2017/746	In Vitro Diagnostic Medical Device Regulation
EN ISO 13485:2016/A11:2021	Medical devices- Quality management systems- Requirements for regulatory purposes
IEC 62304:2006/A1:2015	Medical device software– Software lifecycle processes
EN ISO 14971:2019/A11:2021	Medical devices – Application of risk management to medical devices
IEC 62366-1:2015/A1:2020	Medical devices- Application of usability engineering to medical devices
EN ISO 15223-1:2021	Medical devices- Symbols to be used with medical device labels, labelling and information to be supplied- Part 1: General requirements
MDCG 2019-11	Guidance on qualification and classification of software in Regulation (EU) 2017/745- MDR and Regulation (EU) 2017/746– IVDR
MDCG 2020-1	Guidance on Clinical Evaluation (MDR) / Performance Evaluation (IVDR) of Medical Device Software
MDCG 2020-16 rev.3	Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746

## 1.2 Symbol explanation

### 1.2.1 Manufacturer



Figure 1: Manufac.

To identify the manufacturer of a product. Symbol is accompanied, adjacent to the symbol, by the name and, when applicable, the address of the manufacturer.

ISO 15223-1ISO 7000 (Ref No:3082)

### 1.2.2 Company logo



Figure 2: Logo

### 1.2.3 In Vitro Diagnostic Medical Device

Indicates the item is a medical device.

ISO 1 5223-1IVDR (EU) 2017/746

### 1.2.4 Unique device identifier

Indicates a carrier that contains unique device identifier information

ISO 1 5223-1IVDR (EU) 2017/746



Figure 3: IVD



Figure 4: UDI



Figure 5: CE

### 1.2.5 CE marked product

CE marked product

IVDR (EU) 2017/746

### 1.2.6 Operators manual; operating instructions



Figure 6: IFU

Description: Indicates the need for the user to consult the (electronic) instruction for use ISO 15223-1

## 1.3 About this document

### 1.3.1 Terms and abbreviations

Term	Definition
<b>Harm</b>	Injury or damage to the health of people, or damage to property or the environment.
<b>Hazard</b>	Potential source of harm
<b>Hazardous Situation</b>	Circumstance in which people, property, or the environment is/are exposed to one or more hazards.
<b>Reasonably foreseeable misuse</b>	Use of a product or system in a way not intended by manufacturer, but which can result from readily predictable human behavior
<b>Residual risk</b>	Risk remaining after risk control measures have been implemented.
<b>Risk</b>	Combination of the probability of occurrence of harm and the severity of that harm
<b>Risk analysis</b>	Systematic use of available information to identify hazards and to estimate the risk.
<b>Risk assessment</b>	Overall process comprising a risk analysis and a risk evaluation
<b>Risk control</b>	Process in which decisions are made and measures implemented by which risks are reduced to, or maintained within, specified levels
<b>Risk estimation</b>	Process used to assign values to the probability of occurrence of harm and the severity of that harm
<b>Risk evaluation</b>	Process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk
<b>Risk management</b>	Systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling and monitoring risk
<b>Risk management file</b>	Set of records and other documents that are produced by risk management
<b>Safety</b>	Freedom from unacceptable risk
<b>Severity</b>	Measure of the possible consequences of a hazard
<b>Clinical evidence</b>	Clinical data and performance evaluation results, pertaining to a device of a sufficient amount and quality to allow a qualified assessment of whether the device is safe and achieves the intended clinical benefit(s), when used as intended by the manufacturer

<b>Scientific validity of an analyte</b>	The association of an analyte with a clinical condition or a physiological state
<b>Analytical performance</b>	The ability of a device to correctly detect or measure a particular analyte
<b>Clinical performance</b>	The ability of a device to yield results that are correlated with a particular clinical condition or a physiological or pathological process or state in accordance with the target population and intended user
<b>Performance evaluation</b>	An assessment and analysis of data to establish or verify the scientific validity, the analytical and, where applicable, the clinical performance of a device
<b>Post-market surveillance</b>	All activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions
<b>Recall</b>	Any measure aimed at achieving the return of a device that has already been made available to the end user
<b>Incident</b>	Any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any harm as a consequence of a medical decision, action taken or not taken on the basis of information or result(s) provided by the device
<b>Serious incident</b>	Any incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat
<b>Serious public health threat</b>	An event which could result in imminent risk of death, serious deterioration in a person's state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time
<b>Field safety corrective action</b>	Corrective action taken by a manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market
<b>Field safety notice</b>	A communication sent by a manufacturer to users or customers in relation to a field safety corrective action

Abbreviation	Definition
<b>RM</b>	Risk Management
<b>RMF</b>	Risk Management File
<b>RMP</b>	Risk Management Plan
<b>RMR</b>	Risk Management Report
<b>FMEA</b>	Failure Mode and Effect Analysis
<b>RPN</b>	Risk Priority Number
<b>UDI</b>	Unique Device Identifier
<b>AUC</b>	Area Under the (Receiver Operating) Curve
<b>PPV</b>	Positive Predictive Value
<b>NPV</b>	Negative Predictive Value
<b>LIS</b>	Laboratory Information System
<b>IVD</b>	In Vitro Diagnostic
<b>FDA</b>	Food and Drug Administration

Abbreviation	Definition
<b>ALD</b>	Alcohol-Related Liver Disease
<b>MASLD</b>	Non-Alcoholic Steatotic Liver Disease
<b>MASH</b>	Metabolic dysfunction-associated steatohepatitis
<b>TE</b>	Transient Elastography
<b>LSM</b>	Liver Stiffness Measurement
<b>ELF</b>	Enhanced Liver Fibrosis
<b>INR</b>	International Normalised Ratio
<b>IFU</b>	Instructions For Use
<b>MDSW</b>	Medical Device Software
<b>SaMD</b>	Software as Medical Device
<b>SOUP</b>	Software Of Unknown Provenance
<b>MDCG</b>	Medical Device Coordination Group
<b>MEDDEV</b>	Medical Devices Documents
<b>EMDN</b>	European Medical Device Nomenclature
<b>GP</b>	General Practitioner
<b>GSPR</b>	General Safety and Performance Requirements
<b>IQ</b>	Installation Qualification
<b>OQ</b>	Operational Qualification
<b>PQ</b>	Performance Qualification
<b>PEP</b>	Performance Evaluation Plan
<b>LSP</b>	Literature Search Protocol
<b>PER</b>	Performance Evaluation Report
<b>SoA</b>	State-Of-The-Art
<b>PMS</b>	Post-Market Surveillance
<b>PMPF</b>	Post-Market Performance Follow-Up
<b>MAUDE</b>	Manufacturer And User Facility Device Experience
<b>DoC</b>	Declaration of Conformity
<b>SRN</b>	Single Registration Number

### 1.3.2 Revision history

Revision	Date	Author	Changes	Scope
2.0	2024-02-06	Milos Ilic (MR, Regulatory consultant) milos@evido.health	Initial markdown version	Minor
3.0	2024-03-15	Milos Ilic (MR, Regulatory consultant) milos@evido.health	Change secondary author from Taus to Søren. Update label image file name.	Cosmetic
4.0	2024-07-08	Milos Ilic (MR, Regulatory consultant) milos@evido.health	Update of the label with the new software revision	Minor
5.0	2024-07-12	Milos Ilic (MR, Regulatory consultant) milos@evido.health	Regulatory basis section added	Minor
6.0	2024-08-07	Milos Ilic (MR, Regulatory consultant) milos@evido.health	Cleaned up symbol explanation. No content changes.	Cosmetic
7.0	2025-08-11	Milos Ilic (MR, Regulatory consultant) milos@evido.health	Regular update, no changes needed.	Cosmetic
8.0	2025-09-30	Milos Ilic (MR, Regulatory consultant) milos@evido.health	Label changed to align with the revision number.	Minor

### 1.3.3 Storage location

The original of this document is stored in GitHub.

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