

# Product label

## LiverPRO IVD medical software

Milos Ilic (MR, Regulatory consultant) milos.ilic@sigmasystems.net  
Søren Boll Overgaard (CTO, PRRC) soren@evido.health

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## 1 Product label

### 1.1 Regulatory Basis and External Guidelines

Ref no.	Document ID	Document title	Storage location
1	IVDR (EU) 2017/746	In Vitro Diagnostic Medical Devices Regulation	Eur Lex
2	EN ISO 15223	Medical devices symbols to be used with medical device labels, labelling and information to be supplied Part 1 general requirements	ISO.org

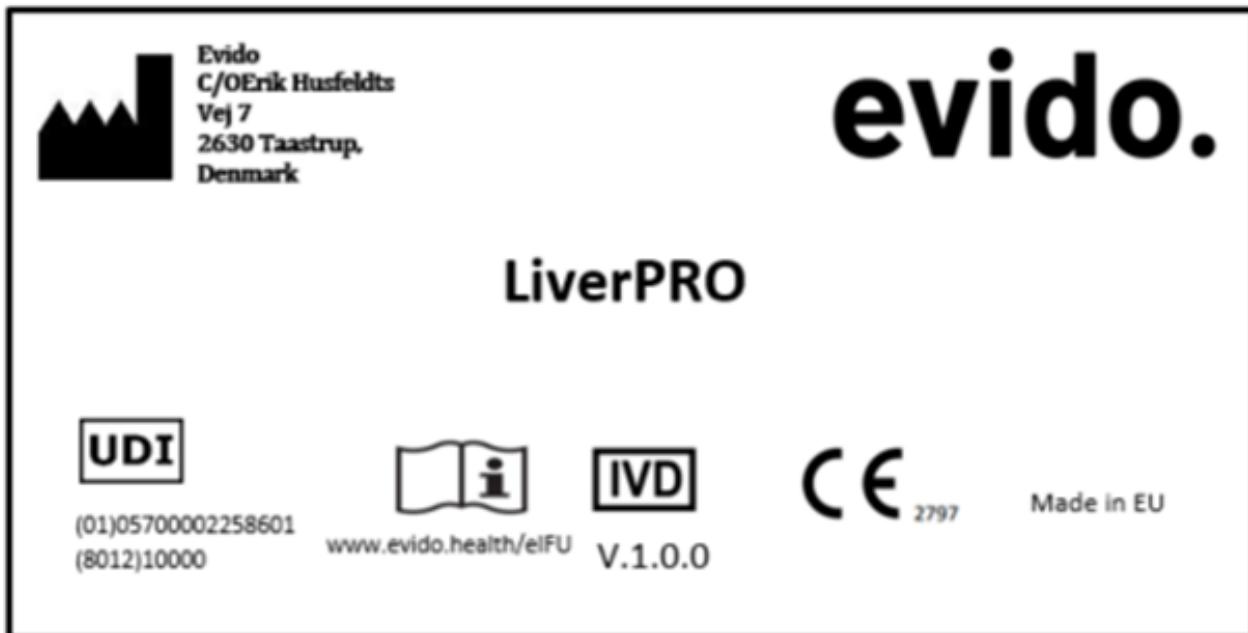
### 1.2 Label

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IVD Medical Software

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LiverPRO



### 1.3 Symbol explanation

Symbol	Name	Standard/Note
	Name: Manufacturer. Description: 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)
	Company logo.	None.
	Name: In Vitro Diagnostic Medical Device. Description: Indicates the item is a medical device.	ISO 15223-1IVDR (EU) 2017/746

Symbol	Name	Standard/Note
	Name: Unique device identifier. Description: Indicates a carrier that contains unique device identifier information	ISO 15223-1IVDR (EU) 2017/746
	CE marked product	IVDR (EU) 2017/746
	Name: Operator's manual; ISO 15223-1 operating instructions Description: Indicates the need for the user to consult the (electronic) instruction for use ISO 15223-1	

## 1.4 About this document

### 1.4.1 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

Term	Definition
<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

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

#### 1.4.2 Revision history

Revision	Date	Author	Changes	Scope
2.0	2024-02-06	Milos Ilic (MR, Regulatory consultant) milos.ilic@sigmasystems.net	Initial markdown version	Minor
3.0	2024-03-15	Milos Ilic (MR, Regulatory consultant) milos.ilic@sigmasystems.net	Change secondary author from Taus to Søren. Update label image file name.	Cosmetic

#### 1.4.3 Storage location

The original of this document is stored in GitHub.

Any print-out of this document or a document stored in different location is considered an “Uncontrolled Copy”.