

Product label

LiverPRO IVD medical software

Milos Ilic (MR, Regulatory consultant) milos.ilic@sigmasystems.net
Taus Holtug (CEO) taus@evido.health

Contents

1	Product label	1
1.1	Regulatory Basis and External Guidelines	1
1.2	Label	1
1.3	Symbol explanation	2
1.4	About this document	3
1.4.1	Terms and abbreviations	3
1.4.2	Revision history	3
1.4.3	Storage location	4

1 Product label

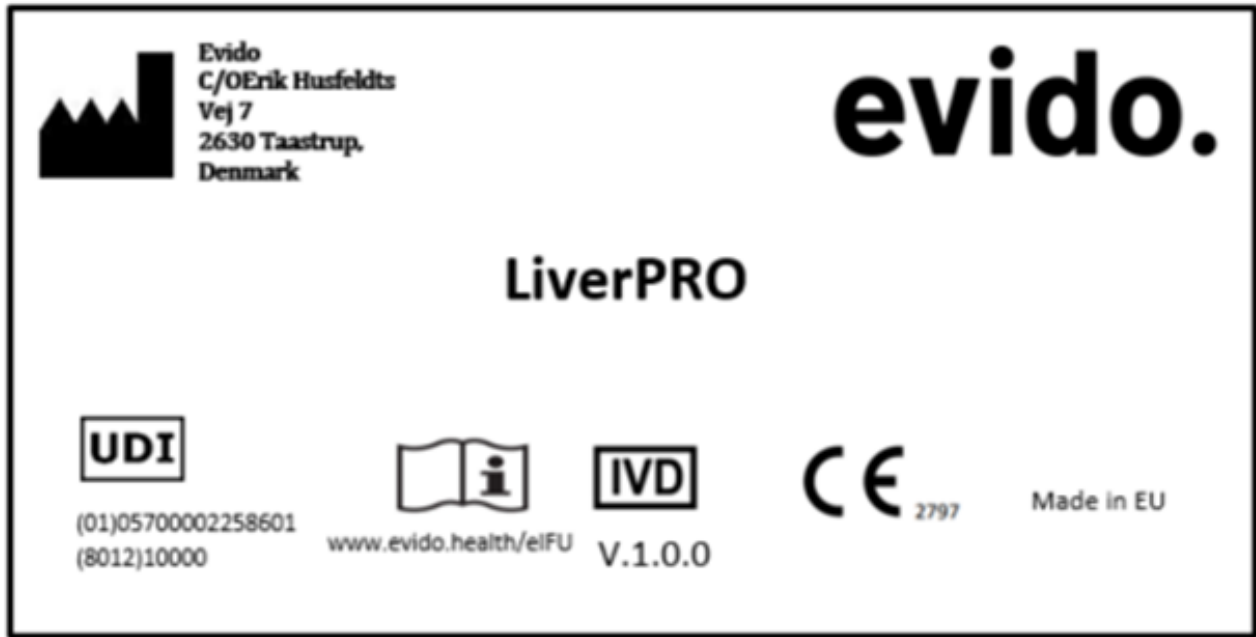
1.1 Regulatory Basis and External Guidelines

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


IVD Medical Software

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
	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

Symbol	Name	Standard/Note
	Name: Operator's manual; operating instructions Description: Indicates the need for the user to consult the (electronic) instruction for use 15223-1	ISO 15223-1

1.4 About this document

1.4.1 Terms and abbreviations

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

Abbreviation	Definition
RM	Risk Management
RMF	Risk Management File
RMP	Risk Management Plan
RMR	Risk Management Report
FMEA	Failure Mode and Effect Analysis
RPN	Risk Priority Number

1.4.2 Revision history

Revision	Date	Author	Changes	Scope
2.0	2024-02-06	Milos Ilc (MR, Regulatory consultant) mi- los.ilic@sigmasystems.net	Initial markdown version	Minor

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”.