Product label

LiverPRO IVD medical software

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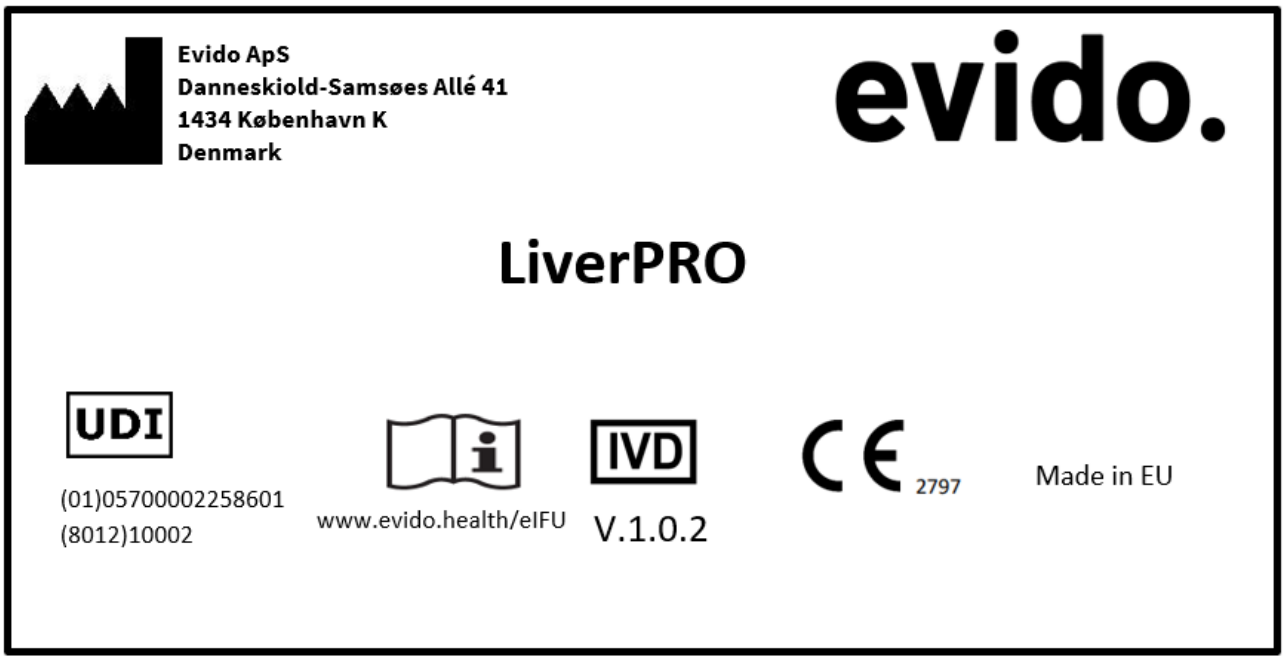
1 Product label

IVD Medical Software

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

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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
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
Clinical evidence	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

Scientific validity of an analyte	The association of an analyte with a clinical condition or a physiological state
Analytical performance	The ability of a device to correctly detect or measure a particular analyte
Clinical performance	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
Performance evaluation	An assessment and analysis of data to establish or verify the scientific validity, the analytical and, where applicable, the clinical performance of a device
Post-market surveillance	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
Recall	Any measure aimed at achieving the return of a device that has already been made available to the end user
Incident	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
Serious incident	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
Serious public health threat	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 |
Field safety corrective action	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
Field safety notice	A communication sent by a manufacturer to users or customers in relation to a field safety corrective action

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
UDI	Unique Device Identifier
AUC	Area Under the (Receiver Operating) Curve
PPV	Positive Predictive Value
NPV	Negative Predictive Value
LIS	Laboratory Information System
IVD	In Vitro Diagnostic
FDA	Food and Drug Administration

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

1.3.2 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
4.0	2024-07-08	Milos Ilic (MR, Regulatory consultant) milos.ilic@sigmasystems.net	Update of the label with the new software revision	Minor
5.0	2024-07-12	Milos Ilic (MR, Regulatory consultant) milos.ilic@sigmasystems.net	Regulatory basis section added	Minor
6.0	2024-08-07	Milos Ilic (MR, Regulatory consultant) milos.ilic@sigmasystems.net	Cleaned up symbol explanation. No content changes.	Cosmetic

1.3.3 Storage location

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