VELA DIAGNOSTICS	TITLE: Symbol Glossary for Vela Diagnostics' US-IVD Products	PS104281	Rev A v1.0	Page 1 of 10

Symbol	Symbol Title	Explanatory Text	Standard Designation Number: Title (*FDA Recognition #*) / Reference Document	Symbol Reference #
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied (*5-134*)	*5.1.1*
EC REP	Authorized representative in the European Community/ European Union	Indicates the authorized representative in the European Community/ European Union	ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied (*5-134*)	*5.1.2*
	Date of manufacture	Indicates the date when the medical device was manufactured	ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied (*5-134*)	*5.1.3*
	Use-by date	Indicates the date after which the medical device is not to be used	ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied (*5-134*)	*5.1.4*
LOT	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified	ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied (*5-134*)	*5.1.5*
REF	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified	ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied (*5-134*)	*5.1.6*

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Symbol	Symbol Title	Explanatory Text	Standard Designation Number: Title (*FDA Recognition #*) / Reference Document	Symbol Reference #
SN	Serial number	Indicate the manufacturer's serial number so that a specific medical device can be identified	ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied *(5-134)*	*5.1.7*
#	Model number	Indicates the model number or type number of a product	ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied *(5-134)*	*5.1.10*
	Do not use if package is damaged and consult instructions for use	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information	ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied *(5-134)*	*5.2.8*
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully	ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied *(5-134)*	*5.3.1*
	Lower limit of temperature	Indicates the lower limit of temperature to which the medical device can be safely exposed	ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied *(5-134)*	*5.3.5*

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Symbol	Symbol Title	Explanatory Text	Standard Designation Number: Title (*FDA Recognition #*) / Reference Document	Symbol Reference #
	Upper limit of temperature	Indicates the upper limit of temperature to which the medical device can be safely exposed	ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied *(5-134)*	*5.3.6*
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed	ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied *(5-134)*	*5.3.7*
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed	ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied *(5-134)*	*5.3.8*
	Do not re-use	Indicates a medical device that is intended for one single use only	ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied *(5-134)*	*5.4.2*
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use	ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied *(5-134)*	*5.4.3*

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Symbol	Symbol Title	Explanatory Text	Standard Designation Number: Title (*FDA Recognition #*) / Reference Document	Symbol Reference #
⚠	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences	ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied *(5-134)*	*5.4.4*
IVD	In vitro diagnostic medical device	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device	ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied *(5-134)*	*5.5.1*
CONTROL	Control	Indicates a control material that is intended to verify the performance of another medical device	ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied *(5-134)*	*5.5.1*
CONTROL –	Negative control	Indicates a control material that is intended to verify the results in the expected negative range	ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied *(5-134)*	*5.5.3*

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Symbol	Symbol Title	Explanatory Text	Standard Designation Number: Title (*FDA Recognition #*) / Reference Document	Symbol Reference #
CONTROL +	Positive control	Indicates a control material that is intended to verify the results in the expected positive range	ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied *(5-134)*	*5.5.4*
∑	Contains sufficient for <*n*> tests	Indicates the total number of tests that can be performed with the medical device	ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied *(5-134)*	*5.5.5*
	For IVD performance evaluation only	Indicates an IVD medical device that is intended to be used only for evaluating its performance characteristics before it is placed on the market for medical diagnostic use	ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied *(5-134)*	*5.5.6*
UDI	Unique device identifier	Indicates a carrier that contains unique device identifier information	ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied *(5-134)*	*5.7.10*
↑↑	This way up	To indicate correct upright position of the transport package.	ISO 7000: Graphical symbols for use on equipment - Registered symbols *(5-124)*	*0623*

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Symbol	Symbol Title	Explanatory Text	Standard Designation Number: Title (*FDA Recognition #*) / Reference Document	Symbol Reference #
Rx Only	For Prescription Use Only	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner	21 CFR 809.10(a)(4) (*N/A*)	N/A
C E	Conformitè Europëenne Mark (CE Mark)	Devices, other than devices for performance evaluation, considered to meet the essential requirements referred to in IVDD 98/79/EC Article 3 must bear the CE marking of conformity when they are placed on the market. Devices, other than devices for performance studies, considered to be in conformity with the requirements of IVDR 2017/746 shall bear the CE marking of conformity.	IVDD 98/79/EC Article 16 (*N/A*) IVDR 2017/746 Article 18 (*N/A*)	N/A

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Symbol	Symbol Title	Explanatory Text	Standard Designation Number: Title (*FDA Recognition #*) / Reference Document	Symbol Reference #
	UL Solutions listing mark for Canada and the USA	Product tested by UL to meet U.S. and Canadian Standards	N/A	N/A
	China RoHS (The restriction of the use of certain hazardous substances in electrical and electronic equipment) mark	This product does not contain any hazardous substances exceeding concentration limits and is a green environmentally friendly product which can be recycled	SJ/T 11364-2014 Marking for the Restriction of Hazardous Substances in Electrical and Electronic Products (N/A)	N/A
	China RoHS (The restriction of the use of certain hazardous substances in electrical and electronic equipment) mark	The product contains at least one hazardous substance but is safe to use during the Environmental Protection Use Period (EPUP). This period is indicated by the number of years shown on the logo. When the period expires, the product should be properly disposed of or recycled.	SJ/T 11364-2014: Marking for the Restriction of Hazardous Substances in Electrical and Electronic Products (*N/A*)	N/A

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Symbol	Symbol Title	Explanatory Text	Standard Designation Number: Title (*FDA Recognition #*) / Reference Document	Symbol Reference #
	CSA listing mark for Canada and the USA	Product was tested and has met the certification requirements for electrical, plumbing and/or mechanical products	N/A	N/A
	FCC Compliance logo	Product complies with the applicable FCC requirements	47 CFR 2.1074(b) (*N/A*)	N/A
	Australia Communications and Media Authority (ACMA) C-tick logo	Device is compliant with applicable EMC requirements	N/A	N/A
	Australia Communications and Media Authority (ACMA) Regulatory Compliance Mark (RCM) symbol	Device is compliant with Electrical Equipment Safety System (EESS) and ACMA's labelling requirements	AS/NZS 4417:2012: Regulatory Compliance Mark For Electrical And Electronic Equipment - Use Of The Mark (*N/A*)	N/A
	Europe Waste Electrical and Electronic Equipment (WEEE) label	Product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling	N/A	N/A

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Symbol	Symbol Title	Explanatory Text	Standard Designation Number: Title (*FDA Recognition #*) / Reference Document	Symbol Reference #
	Nationally Recognised Testing Laboratory (NRTL) TÜV SÜD Mark	Product has been tested for safety in the workplace according to the US authorities and Canadian requirements of the US Occupational Safety & Health Administration by TÜV SÜD under the OSHA NRTL program.	N/A	N/A
COMP	Kit Component	Component that is part of the kit	N/A	N/A
NUM	Number of Component	Number of components present in the kit	N/A	N/A
CONT	Volume Content	Volume Content of respective Kit Components	N/A	N/A
MAT	Manufacturer Material Number	Material Number of the Kit	N/A	N/A
	Harmful	An immediate skin, eye or respiratory tract irritant, or narcotic.	ST/SG/AC.10/30/Rev.9: Globally Harmonized System of Classification and Labelling of Chemicals (Rev.9, 2021) (*N/A*)	N/A

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Symbol	Symbol Title	Explanatory Text	Standard Designation Number: Title (*FDA Recognition #*) / Reference Document	Symbol Reference #
	Flammable	Flammable materials or substances liable to self-ignite when exposed to water or air (pyrophoric), or which emit flammable gas.	ST/SG/AC.10/30/Rev.9: Globally Harmonized System of Classification and Labelling of Chemicals (Rev.9, 2021) (*N/A*)	N/A
	Health Hazard	A cancer-causing agent (carcinogen) or substance with respiratory, reproductive or organ toxicity that causes damage over time (a chronic, or long-term, health hazard).	ST/SG/AC.10/30/Rev.9: Globally Harmonized System of Classification and Labelling of Chemicals (Rev.9, 2021) (*N/A*)	N/A
	Corrosive	Materials causing skin corrosion/burns or eye damage on contact, or that are corrosive to metals.	ST/SG/AC.10/30/Rev.9: Globally Harmonized System of Classification and Labelling of Chemicals (Rev.9, 2021) (*N/A*)	N/A
	Cut here	Location on the label for user to cut	N/A	N/A