
























GLOSSARY OF SYMBOLS - IVD

Symbol	Title	Reference #	Applicable Standard & Recognition Number
	Atmospheric Pressure Limitation	5.3.9	042:AAMI/ANSI/ EN ISO15223-1:2021
	Authorized Representative in the European Community	5.1.2	042:AAMI/ANSI/ EN ISO15223-1:2021
	Batch Code	5.1.5	042:AAMI/ANSI/ EN ISO15223-1:2021
	Biological Risks	5.4.1	042:AAMI/ANSI/ EN ISO15223-1:2021
	Catalog Number	5.1.6	042:AAMI/ANSI/ EN ISO15223-1:2021
	Caution	5.4.4	042:AAMI/ANSI/ EN ISO15223-1:2021
	Consult Instructions For Use	5.4.3	042:AAMI/ANSI/ EN ISO15223-1:2021
	Contains biological material of animal origin	5.4.8*	042:AAMI/ANSI/ EN ISO15223-1:2021
	Contains hazardous substances	5.4.10*	042:AAMI/ANSI/ EN ISO15223-1:2021
	Contains sufficient for <n> Tests	5.5.5	042:AAMI/ANSI/ EN ISO15223-1:2021
	Date of Manufacture	5.1.3	042:AAMI/ANSI/ EN ISO15223-1:2021
	Do Not Re-use	5.4.2	042:AAMI/ANSI/ EN ISO15223-1:2021
	Fragile, Handle with Care	5.3.1	042:AAMI/ANSI/ EN ISO15223-1:2021
	Humidity Limitation	5.3.8	042:AAMI/ANSI/ EN ISO15223-1:2021

*Approved symbols currently awaiting ISO harmonization.

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Symbol	Title	Reference #	Applicable Standard & Recognition Number
	In Vitro Diagnostic Medical Device	5.5.1	042:AAMI/ANSI/ EN ISO15223-1:2021
	Keep Away from Sunlight	5.3.2	042:AAMI/ANSI/ EN ISO15223-1:2021
	Keep Dry	5.3.4	042:AAMI/ANSI/ EN ISO15223-1:2021
	Lower Limit of Temperature	5.3.5	042:AAMI/ANSI/ EN ISO15223-1:2021
	Manufacturer	5.1.1	042:AAMI/ANSI/ EN ISO15223-1:2021
	Sterilized Using Irradiation	5.2.4	042:AAMI/ANSI/ EN ISO15223-1:2021
	Temperature Limit	5.3.7	042:AAMI/ANSI/ EN ISO15223-1:2021
	Use-By Date	5.1.4	042:AAMI/ANSI/ EN ISO15223-1:2021
	Warning: Low temperature/Freezing conditions	054	ISO 7010:2019