









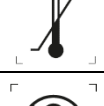

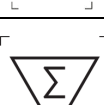

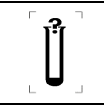
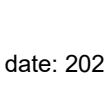




This document specifies symbols used on **BÜHLMANN Kits**, according ISO 15223-1:2021.

Symbol	Title	Description
	Manufacturer	This symbol shall be accompanied by the name and address of the manufacturer adjacent to the symbol.
	Authorized representative in the European Community/ European Union	This symbol shall be accompanied by the name and address of the authorized representative, adjacent to the symbol.
	Date of manufacture	This symbol shall be accompanied by a date to indicate the date of manufacture.
	Use-by date	This symbol shall be accompanied by a date to indicate that the medical device should not be used after the end of the year, month or day shown.
	Batch code	This symbol shall be accompanied by the manufacturer's batch code adjacent to the symbol.
	Catalogue number	This symbol shall be accompanied by the manufacturer's catalogue number adjacent to the symbol.
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.

Symbol	Title	Description
	Importer	This symbol shall be accompanied by the name and address of the importing entity adjacent to the symbol.
	Distributor	This symbol shall be accompanied by the name and address of the distributing entity adjacent to the symbol.
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use
	Temperature limit	The upper and lower limits of temperature shall be indicated adjacent to the upper and lower horizontal lines.
	Do not re-use	Indicates a medical device that is intended for one single use only.
	<i>In vitro</i> diagnostic medical device	Indicates a medical device that is intended to be used as an <i>in vitro</i> diagnostic medical device.
	Contains sufficient for <n> tests	Indicates the total number of tests that can be performed with the medical device. The number of tests that can be performed with the medical device shall appear adjacent to the symbol.
	Unique device identifier	This symbol may be used when multiple data carriers are present on the label. If used, this symbol shall be placed adjacent to the unique device identifier carrier.
	For IVD Performance evaluation only	Indicates an <i>in vitro</i> diagnostic 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.

**Additional Symbols used (not covered by ISO standards):**

Symbol	Title	Description
<b>CE 0123</b>	CE mark with four-digit identification number of NB	A <b>CE</b> marking followed by a four-digit identification number indicates that a Notified Body (NB) was involved in conformity assessment. CE 0123 shows that TÜV SÜD was the Notified Body involved in conformity assessment.
<b>CE</b>	CE mark	On commercial products, the letters <b>CE</b> (as the logo) mean that the manufacturer or importer affirms the good's conformity with European health, safety, and environmental protection standards according IVDD or IVDR.
	Restricted devices in US	Indicates a medical device that can only be sold, distributed or used upon the order of an authorized healthcare provider in the USA.
	NA	The Unique Device Identification (UDI) is a worldwide system for uniform product labelling of medical devices and allows to trace medical devices quickly and easily from the manufacturer to the user.