ellume

COVID-19 home test

GLOSSARY OF SYMBOLS

Symbol	Symbol Title	Explanatory Text
	Manufacturer	Indicates the medical device manufacturer
	Use by date	Indicates the date after which the medical device is not to be used
	Batch code	Indicates the manufacturer's batch code to identify the batch or lot
	Catalog number	Indicates the manufacturer's catalog number to identify the medical device
	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide
	Temperature limit	Indicates the temperature limits to which the medical devie can be safely exposed

Symbol	Symbol Title	Explanatory Text
	Do not reuse	Indicates a medical device that is intended for one use, or for uses on a single patient during a single procedure
	Consult instructions for use	Indicates the need for the user to consult the instructions for use
	In vitro diagnostic medical device	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device
	Do not use if package is damaged	Indicates a medical device that should not be used if the packaging has been damaged or opened
	CE marking	Signifies European technical conformity
	Medical Device	Indicates the item is a medical device
	Federal Communications Commission (FCC) Logo	Meets FCC requirements per 47 CFR § 15.247
	Bluetooth® Logo	Indicates that the device is Bluetooth® enabled
	For self-testing	Indicates the device is a self-test in vitro diagnostic device. This means a lay person can use it without formal healthcare or medical experience

The Ellume COVID-19 Home Test is a self-test in vitro diagnostic device.

In USA - This product has not been FDA cleared or approved but has been authorized by FDA under an Emergency Use Authorization (EUA). This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. This product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.