BESA License Key 2.0 - Product Symbols Meaning

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O Approved, Changed on: October 9th 2023 at 1:31:11 PM (UTC)



Symbols-Meaning

This document provides all symbols used with respect to:

BESA License Key 2.0.1.0

UDI (human readable) related to this product is available in "BESA License Key 2.0 - Instructions for Use"

AIDC (Barcode) UDI Labeling of Product Version:

AIDC (automatic identification and data capture) are created individually for each BESA License Key, and is available on the label of BESA Box. Example:



Symbol	Occurrence at BESA Product or accompanying documents, website	Meaning	Source of Symbol
C€	BESA License Key, marked on device	The CE marking certifies that this product fulfills the essential requirements of: the Medical Device Regulation MDR (EU) 2017/745	Use of CE sign regulated by Medical Device Regulation MDR (EU) 2017/745
	BESA License Key, marked on device	Indicates the contact address for BESA, the manufacturer of the device is available in document "BESA License Key 2.0 - Instructions for Use"	ISO 15223-1:2021
elFU indicator	BESA License Key	Indicates the need for the user to consult the instructions for use	ISO 15223-1:2021
SN	BESA License Key	Indicates the manufacturer's serial number so that a specific medical device can be identified	ISO 15223-1:2021

UDI	BESA License Key	Indicates a carrier that contains unique device identifier information	ISO 15223-1:2021
	BESA Shipping packaging	Indicates the temperature limits to which the medical device can be safely exposed	ISO 15223-1:2021
	BESA Shipping packaging	Indicates the range of humidity to which the medical device can be safely exposed	ISO 15223-1:2021
	BESA Shipping packaging	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 15223-1:2021
F©	BESA License Key, marked on device	FCC-marking - Compliance to US requirements with respect to electromagnetic interference (EMC) from the device	Regulated by US, more info at: Federal Communications Commission Note: provided to BESA License Key by Thales
	BESA License Key, marked on device	This symbol indicates that when the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling. By separating this product from other household-type waste, the volume of waste sent to incinerators or land-fills will be reduced and natural resources will thus be conserved.	Directive 2012/19/EU WEEE (Waste Electrical and Electronic Equipment) Note: provided to BESA License Key by Thales
10	BESA License Key, marked on device	Defines the Environment- Friendly Use Period (EFUP) as 10 years after production. Note: production date of respective BESA License Key can be found on label of BESA Box.	China RoHS GB/T 26572-2011 Note: provided to BESA License Key by Thales
	BESA License Key, marked on device	Refer to instruction manual/booklet	ISO 7010-M002
C	BESA License Key, marked on device	Product certification which ensures the conformity of	Korean regulations

	products to Korean safety	
	standards	

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1	Mon, Oct 9, 2023, 13:31:11 PM	>> *Action: approve, OK, Approval: Approved (State: Non-QM Approval, Mon, Oct 9, 2023, 13:31:11 PM)	None

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