BESA License Key 2.0 - Product Symbols Meaning

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• Approved , Changed on: January 22nd 2024 at 1:49:02 PM (UTC)



Symbols-Meaning

This document provides all symbols used with respect to:

BESA License Key 2.0 including all subversions

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
CE	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

	DE0.11:		100 45000 1 5551
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
FC	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
	BESA License Key, marked on device	Product certification which ensures the conformity of	Korean regulations

	products to Korean safety	
	standards	

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Change History (valid revision number)

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▼ Template Change History

TEMPLATE	TEMPLATE Version	Effective Date	Version Notes
BESA Product Symbols Meaning	1	Thu, 16 Mar 2023 07:02:54 GMT	None
BESA Product Symbols Meaning	2	Tue, 21 Mar 2023 14:36:24 GMT	None
BESA Product Symbols Meaning	3	Tue, 02 May 2023 07:37:57 GMT	None
BESA Product Symbols Meaning	4	Tue, 02 May 2023 07:40:08 GMT	None
BESA Product Symbols Meaning	5	Wed, 24 May 2023 14:26:05 GMT	None
BESA Product Symbols Meaning	6	Fri, 23 Jun 2023 06:19:40 GMT	None
BESA Product Symbols Meaning	7	Mon, 09 Oct 2023 12:01:45 GMT	None

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