


BESA License Key 3.0 - Product Symbols Meaning

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 Approved, Changed on: March 25th 2024 at 3:23:33 PM (UTC)



Symbols-Meaning

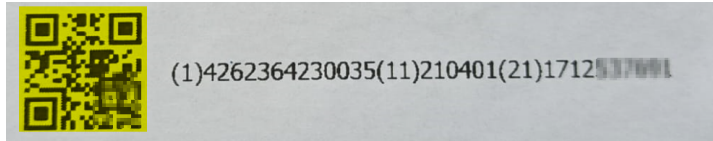
This document provides all symbols used with respect to:



BESA License Key 3.0 (all sub-versions of the product included)







UDI (human readable) related to this product is available in “BESA License Key 3.0 - 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
	Available in accompanying document “BESA License Key 3.0 - Instructions for Use”	This product bears a CE sign as drawn up by the manufacturer. Due to the size of the BESA License Key, it is not marked on the device.	Use of CE sign as defined by manufacturer for device being compliant to directive 2014/30/EU.
	Available in accompanying document “BESA License Key 3.0 - Instructions for Use”	Indicates the contact address for the manufacturer of the device	ISO 15223-1:2021

 <p>eIFU indicator</p>	<p>Available on the label of packaging, BESA Box</p>	<p>Indicates the need for the user to consult the instructions for use</p>	<p>ISO 15223-1:2021</p>
	<p>Available in accompanying document "BESA License Key 3.0 - Instructions for Use"</p>	<p>Indicates a carrier that contains unique device identifier information, is created based on the manufacturer's serial number so that a specific medical device can be identified</p>	<p>ISO 15223-1:2021</p>
	<p>BESA shipping packaging</p>	<p>Indicates the temperature limits to which the medical device can be safely exposed</p>	<p>ISO 15223-1:2021</p>
	<p>BESA shipping packaging</p>	<p>Indicates the range of humidity to which the medical device can be safely exposed</p>	<p>ISO 15223-1:2021</p>
	<p>BESA shipping packaging</p>	<p>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</p>	<p>ISO 15223-1:2021</p>
	<p>BESA shipping packaging</p>	<p>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.</p>	<p>Directive 2012/19/EU WEEE (Waste Electrical and Electronic Equipment)</p>

	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: https://www.fcc.gov/ Note: provided to BESA License Key by Thales
	BESA License Key, marked on device	Product certification which ensures the conformity of products to Korean safety standards	Korean regulations

Note: the declaration of conformity by manufacturer can be requested from BESA.

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Change History (valid revision number)

Version	Effective Date	Approvals	Version Notes
1	Mon, Mar 25, 2024, 15:23:33 PM	>> *Action: approve, OK, Approval: Approved (State: Non-QM Approval, Mon, Mar 25, 2024, 15:23:33 PM)	None

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

TEMPLATE	TEMPLATE Version	Effective Date	Version Notes
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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