


BESA MRI 3.0 - Product Symbols

Documents are subject to workflows, and content shall only be used if the content is approved (indicated by a green ring-symbol)

 Approved , Changed on: May 16th 2024 at 2:32:21 PM (UTC)







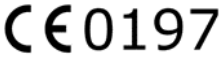




Symbols-Meaning

This document provides all symbols used with respect to:

BESA MRI 3.0.0.1

UDI (human readable) related to this product is available in Instructions for Use
AIDC (Barcode) UDI Labeling of Product Version:
N/A

Symbol	Occurrence at BESA Product or accompanying documents, website	Meaning	Source of Symbol
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<p>About box:</p>	<div style="display: flex; justify-content: space-between;"> <div style="text-align: center;">  </div> <div> <p>Version 3.0 May 2024</p> <p>Copyright © 2024 - BESA GmbH. All rights reserved.</p> </div> </div> <div style="background-color: #0056b3; color: white; padding: 10px; margin-top: 10px;"> <div style="display: flex; align-items: center;">  <p style="font-size: 0.8em; line-height: 1.2;"> The BESA MRI software is licensed for use on a single computer system. All warranties of any kind are hereby disclaimed, including all warranties of fitness for a particular purpose. In countries where the CE certification is not recognized, it is not allowed to use this software directly or indirectly for medical diagnosis and/or treatment of humans. Not for diagnostic use in the United States of America! </p> </div> <p style="text-align: center; font-weight: bold; margin-top: 10px;">Read the User Manual before first use!</p> </div> <div style="margin-top: 10px;"> <p style="font-size: 1.2em; font-weight: bold;">CE0197</p> <div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div style="font-size: 0.8em;"> <p>MD UDI (1)4262364230011 (8012)03000001</p> <p> BESA GmbH, Freihamer Str. 18, 82166 Graefelfing, Germany</p> <p> https://www.besa.de/home/downloads/besa-mri/</p> </div> <div style="font-size: 0.8em;"> <p>BESA MRI makes use of unmodified third-party libraries. Please see C:\Program Files\BESA\MRI_3_0_x64\Utilities\License\License acknowledgements.pdf for license acknowledgements.</p> <p>www.besa.de</p> </div> </div> <div style="text-align: center; margin-top: 10px;"> <input type="button" value="OK"/> </div> </div>		
	<p>About Box, Declaration of Conformity, Instructions for Use</p>	<p>The CE marking certifies that this product fulfills the essential requirements of the Medical Devices Directive MDD 93 /42 / EEC. The number 0197 represents the identification number of the Notified Body</p>	<p>Use of CE sign regulated by the Medical Device Regulation MDR (EU) 2017/745</p>
	<p>About Box, Instructions for Use</p>	<p>Indicates the medical device manufacturer</p>	<p>ISO 15223-1:2021</p>
 eIFU indicator	<p>About Box, Instructions for Use</p>	<p>Indicates the need for the user to consult the instructions for use</p>	<p>ISO 15223-1:2021</p>
	<p>About Box, Instructions for Use</p>	<p>Indicates the item is a medical device</p>	<p>ISO 15223-1:2021</p>
	<p>About Box, Instructions for Use</p>	<p>Indicates a carrier that contains unique device identifier information</p>	<p>ISO 15223-1:2021</p>

	Instructions for Use	Indicates that the original medical device information has undergone a translation which supplements or replaces the original information	ISO 15223-1:2021
	BESA MRI User manual	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences	ISO 15223-1:2021
	BESA Box BESA Booklet Image Brochure	Symbol used in BESA booklet, refers to BESA MRI	372dpi
	BESA MRI, within software	Used as icon for: desktop shortcuts, Start Menu, Program info entry on target PC	372dpi
	BESA License Search, within BESA software	Used by BESA programs. Used as icon for: Start Menu entry on target PC	372dpi
	BESA UpdateIni, within BESA software	Used by BESA programs. Used as icon for: Start Menu entry on target PC	372dpi

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Change History (valid revision number)

Version	Effective Date	Approvals	Version Notes
1	Thu, May 16, 2024, 08:42:39 AM	>> *Action: approve, HB, Approval: Approved (State: Non-QM Approval, Thu, May 16, 2024, 08:42:39 AM)	none
2	Thu, May 16, 2024, 14:32:21 PM	>> *Action: approve, MK, Approval: QM Approval (State: QM Approval, Thu, May 16, 2024, 14:32:21 PM)	Replaced confidential footer with non- confidential footer

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