

BESA License Key 2.0 - Intended Use and Product Classification

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● Approved , Changed on: September 22nd 2023 at 9:54:44 AM (UTC)



Intended Use and Product Classification

Purpose:

This document contains information concerning the intended use and the product classification of BESA License Key 2.0 in English language.

Product Name

BESA License Key 2.0

Intended Use

The BESA License Key 2.0 provides copy protection for BESA software and can protect one or more BESA programs. Individual BESA products or modules can be activated using HASP features (slots) within the BESA License Key 2.0. These are USB dongles which provide the license/s locally or within a network.

- The purpose of the BESA License Key 2.0 is to provide the licensing for BESA products.
- The BESA License Key 2.0 is only to be used in accordance with the intended use.
- The BESA License Key 2.0 is designed for use with the following BESA products:
 - BESA Research (7.X; incl. all sub-versions)
 - BESA MRI (3.X; incl. all sub-versions)
 - BESA Connectivity (1.X and 2.X; incl. all sub-versions)
 - BESA Statistics (2.X; incl. all sub-versions)
- The BESA License Key 2.0 is intended to be used:
 - Locally – attached to the PC running the BESA program (see above), or
 - Remotely within a LAN

Please note that the BESA License Key 2.0 needs to be attached to the machine or the network throughout the entire session of the relevant BESA program.

Please note that in a remote access scenario, the required drivers for using the BESA License Key 2.0 (available for installation as "HASPUsetup.exe") need to be installed locally on the machine running the BESA program, and on the machine to which the BESA License Key 2.0 is attached.

- The BESA License Key 2.0 is not intended to be used over a VPN tunnel or other remote LAN access methods.
- The BESA License Key 2.0 is not for commercial use, such as fee-based analysis services.

Specific Medical Purposes

BESA License Key has no specific medical purpose.

Intended User

The intended users are:

- Administrator:
 - Installation of software required by the BESA License Key 2.0.
 - Configuration of network environment (if applicable).
- User of BESA programs:
 - Installation of license updates provided by BESA GmbH.

Please note, that beside potential installation of license updates, if initial configuration of BESA License Key 2.0 (and network environment, if not used locally) has been done correctly, no action from user of BESA products with respect to License Key 2.0 required.

BESA GmbH assumes no liability for unauthorized access to, or unauthorized use of the product.

The product shall not be used by children, laypersons or patients.

Product Classification

According to Regulation (EU) 2017/745, BESA License Key 2.0 is not a medical product in itself, but to be classified as an accessory product to BESA products.

Medical Device Class	
BESA License Key is an 'accessory for a medical device'	according to MDR - EU Regulation 2017/745; Article 2
Designed for long term use	according to MDR - EU Regulation 2017/745; ANNEX VIII: CLASSIFICATION RULES; CHAPTER I: DEFINITIONS SPECIFIC TO CLASSIFICATION RULES; 1. DURATION OF USE; Section 1.3
Class: no class assigned, according to classification BESA License Key is not a medical device.	according to MDR - EU Regulation 2017/745, Article 2: Definitions
Software Safety Classification	
BESA License Key is not a medical device, therefore no safety classification is required	IEC 62304:2006/AMD1:2015

Change History (valid revision number)

Version	Effective Date	Approvals	Version Notes
1	Fri, Sep 22, 2023, 07:41:14 AM	>> *Action: approve, MK, Approval: QM Approval (State: QM Approval, Fri, Sep 22, 2023, 07:41:14 AM)	None
2	Fri, Sep 22, 2023, 09:54:44 AM	>> *Action: approve, OK, Approval: Approved (State: Non-QM Approval, Fri, Sep 22, 2023, 09:54:44 AM)	None

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