

BESA License Key 2.0 - Instructions for Use

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: October 9th 2023 at 1:36:08 PM (UTC)



Instructions for Use

Purpose

This document contains the instructions for use and safety instructions, as well as technical description for this BESA License Key 2.0 in English language.


Instructions for Use

The referenced term "BESA License Key 2.0" includes all sub-versions of the product.

This document, and following documents form the complete Instructions for Use for this BESA product:

- BESA License Key 2.0 - Intended Use and Product Classification
- BESA License Key 2.0 - Instructions for Use
 - How to update BESA Licenses
 - How to use BESA licenses on a local network
 - Communication problems with Sentinel License Managers
- BESA License Key 2.0 - External Release Notes
- BESA License Key 2.0 - Installation and Un-Installation
- BESA License Key 2.0 - Product Symbols Meaning

Current and previous versions of documents are available on BESA website:

 eIFU indicator	User Documentation
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It is mandatory to read the complete Instructions for Use documents, before using the product.

At any time during the lifetime of this product, you can request the above-mentioned documents in printed paper form at no additional cost.

Product Name

BESA License Key 2.0

The referenced term "BESA License Key 2.0" includes all subversions of the product. BESA License Key 2.0 is an accessory product to BESA medical devices.


Product Picture



Product UDI

UDI	
UDI-DI:	(1)4262364230035
UDI-PI:	NOTE: the UDI-PI is individually for each License Key 2.0, including the serial number. It is available on the label applied to BESA Box.

Manufacturer

	Thales DIS CPL Deutschland GmbH Werinherstr. 81 81541 München
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NOTE: With the use of the symbol on the BESA License Key 2.0 itself, BESA does not claim manufacture ship, but rather provides a contact address.

Symbols used for Product

CE	This product is marked with a CE sign.
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Representative inside the European Union

N/A

Life cycle

The life cycle of all dongles subsumed under BESA License Key 2.0 ends on 2031-04-01.

Note:

The manufacturer of the BESA License Key 2.0 defines the battery life / warranty as 4 years after production.

In compliance with the statements of the manufacturer, BESA acknowledges the life cycle of the BESA License Key 2.0 as 10 years. (Note: even if a battery has run out of power and is not functioning, the BESA License Key 2.0 will still provide licenses for BESA products. The battery is only required if at least one license on the BESA License Key 2.0 is a time-limited license. This scenario may apply if there is a transition phase where a BESA product has been ordered and delivered but payment has not yet been received by BESA. Once payment has been received, a perpetual license is provided to the customer).

BESA takes care only to supply BESA License Keys with a life cycle which is at least as long as the life cycle of the accompanying BESA products.

Incident

In case of a serious incident, an incident or near-incident caused by the BESA License Key, the licensee should directly report to incident@besa.de, follow the guidelines stipulated on the BESA website. ([🔔 Incident](#)).

Safety Instructions and Technical Description

Licensing System

BESA products are protected by the Sentinel LDK licensing system as developed by Thales.

The licensing system requires a USB key – that is, the BESA License Key 2.0 – and the device drivers to access the USB key.

If you selected the Install BESA License Key drivers option at the final stage of the installation, the device drivers for the BESA License Key 2.0 have been installed automatically on your computer. In order for BESA products to be run, a BESA License Key with valid license information must be attached to a USB port on a computer in your local area network. If you have not yet received it, you can obtain the BESA License Key from our sales department by contacting sales@besa.de.

If you have received a license update for your BESA License Key and you are not sure how to apply it, please refer to “[How to update BESA licenses](#)”.

If you have attached the BESA License Key 2.0 (USB key) directly to your computer or server and are not able to start the relevant BESA product, please refer to “[How to use BESA licenses on a local network](#)” or “[Communication problems with Sentinel License Managers](#)”.

System Requirements

The BESA License Key 2.0 is an essential accessory product to BESA products, and shall either be subject to constant supervision, or shall be connected to machines located in areas with access restriction. Failure of the IT-network and/or operating system on which the BESA License Key 2.0 is used, or failure of the BESA License Key 2.0 in general, may render BESA products which use the BESA License Key 2.0 as an accessory as unusable.

- For the purposes of communication between BESA products and the BESA License Key 2.0, the manufacturer uses TCP and UDP ports 1947. Please make sure to open these ports within your network or IT environment in order to enable the required communication. Once the license key runtime environment is installed, you can find more information on settings, security and general topics concerning the BESA License Key 2.0 under the following link:
<http://localhost:1947> > Help
- HASPUserSetup.exe installs the runtime environment and drivers required by the BESA License Key 2.0.

⚠ Important: Make sure to regularly check [🔔 BESA License Key](#) and apply updates for HASPUserSetup.exe if available.

The supplied runtime environment is provided by BESA “as is”, and according to the manufacturer is compatible with computers running the following operating systems:

(NOTE: Information supplied by manufacturer (Thales))

Windows (x64 and x86)	<ul style="list-style-type: none">• Windows Server 2016• Windows Server 2019• Windows Server IoT 2019• Windows Server 2022• Windows Server IoT 2022• Windows 10 IoT Enterprise 2019 LTSC• Windows 10 IoT Enterprise 2021 LTSC• Windows 10 22H2• Windows 11 22H2• Windows 11 ARM 22H2
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- The BESA License Key 2.0 is designed to be attached to a USB 2.0 or USB 3.0 port. Please note that you may need to use an adapter to attach the BESA License Key 2.0 to your PC (the adapter is not included).
- The BESA License Key 2.0 has been tested by BESA on the following operating systems:
 - Windows 11 Pro 21H2 (x64)
 - Windows 10 Pro version 22H2 (x64)

Please note, that changes of the hardware and software platforms (e.g., with patches/updates of antivirus/firewall software, system libraries, firmware, and others) and/or changes to the IT network may result in the possibility of safety and/or security vulnerabilities, and/or reduced functionality of BESA License Key 2.0. It is recommended to use the system combinations as defined within this document.

Please note, that the use of BESA License Key 2.0 on an IT-network could result in previously unidentified risks to patients, users or third parties, and that the user is responsible to identify, analyze, evaluate, and control these risks. Any subsequent changes to the IT-network could introduce new risks and require additional analysis.

Data Protection

BESA License Key 2.0 does not store any data.

Use in combination with other products

The license key is allowed to be used as an accessory product for the following BESA products:

- BESA Research (7.X; incl. all sub-versions)
- BESA MRI (3.X; incl. all sub-versions)
- BESA Connectivity (1.X; 2.X, incl. all sub-versions)
- BESA Statistics (2.X; incl. all sub-versions)

BESA releases are constantly checked with other installations (e.g. MS Office etc.) on the same hardware or software platforms as defined in section System Requirements.

If any incompatibilities are observed, they are documented within the External Release Notes of the product. For further questions and information please use the channels provided on [Home](#).

Application Environment

Please note: It is the user's responsibility to ensure the safety of combined medical or medical-&-non-medical-devices particularly installed in the patient environment (whether in institutes, clinics or practitioners location).

The user of our product has to ensure that such combination fulfills the same safety condition as a single medical device according to IEC 60601-1.

Such combination with any non-medical device establishes an "in-house medical system" – observe the latest Medical Device Operator Ordinance (e.g. MedBetreiberVerordnung, Germany 2020) or your national Operator Laws. We recommend you to document / retrace our software version/updates installed in your facility / network in a MPG-Medizingeräte-Buch (medical facilities book), similar to those needed for hardware.

This BESA product does not affect the possibility of using any medical computer within patient environment.

BESA GmbH is not liable for any use/installation beyond the defined PC network.

Installation and Un-Installation

Please refer to a separate document "[BESA License Key 2.0 - Installation and Un-Installation](#)".

Exclusions for Use

N/A

Contraindication to patients

N/A

BESA is not liable for the use outside of the rules defined in the instructions for use documents.

Manufacture, Transport, Storage and Usage conditions

Environmental conditions for manufacturing

N/A

Environmental conditions for Transport, Storage and Usage

During extended periods of transport, storage and usage please observe the following conditions:

Temperature: - 20°C to 60°C

Humidity: 0% to 95%

Disposal information

The BESA License Key 2.0 and the box in which it is delivered must be disposed of in compliance with national guidelines on environmental protection.

Countries and Markets

This BESA product may be sold in the following countries and markets:

Austria	Germany	Malta	Spain	China	Saudi Arabia
Belgium	Greece	Macedonia	Sweden	Colombia	Singapore
Bulgaria	Hungary	Netherlands	Switzerland	India	South Africa
Croatia	Iceland	Norway	Turkey	Iran	South Korea
Cyprus	Ireland	Poland	United Kingdom	Israel	Taiwan
Czech Republic	Italy	Portugal	Australia	Japan	Thailand
Denmark	Latvia	Romania	Argentina	Malaysia	Turkmenistan
Estonia	Liechtenstein	Serbia	Brazil	Mexico	UAE
Finland	Lithuania	Slovakia	Canada	New Zealand	USA
France	Luxembourg	Slovenia	Chile	Qatar	

Change History (valid revision number)

Version	Effective Date	Approvals	Version Notes
1	Fri, Oct 6, 2023, 09:53:17 AM	>> *Action: approve, MK, Approval: QM Approval (State: QM Approval, Fri, Oct 6, 2023, 09:53:17 AM)	None
2	Mon, Oct 9, 2023, 13:36:08 PM	>> *Action: approve, MK, Approval: QM Approval (State: QM Approval, Mon, Oct 9, 2023, 13:36:08 PM)	None

Attachments

Attachment	Description
N/A	N/A

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