Declaration of Conformity

Confirmation is hereby given that the product

BESA® License Key 2.0

meets the provision of the Regulation (EU) MDR 2017/745 for accessory products for medical devices.

BESA License Key 2.0 is an **accessory product for medical devices** according to Regulation (EU) MDR 2017/745, Article 2. Designed for long term use, according to Regulation (EU) MDR 2017/745; Annex VIII: Classification rules; Chapter I: Definitions specific to classification rules; 1. duration of use; section 1.3:

Class I according to Regulation (EU) MDR 2017/745, Annex II; 6.3. Rule 11 and 6.5. Rule 13.

The product is marked with CE

Aforesaid is declared under the sole responsibility of:

BESA GMBH
Freihamer Str. 18
82166 Graefelfing, Germany

This declaration is valid for all Licence Keys with version number as mentioned above, including subversions, or until withdrawn by BESA GmbH due to modification of product or of technical requirements, of supplier certificates or due to end of product lifecycle.

Hardware and software basis is used by BESA GmbH for creation of the BESA License Key - an USB dongle provided by manufacturer Thales DIS France SA, 92190 Meudon. Thales declares conformity for the dongle to current EU and international regulations, e.g.: UKCA Declaration of Conformity, EMC Directive 2014/30/EU, RoHS 2011/65/EU, REACH Regulation 1907/2006/EC, WEEE 2012/19/EU, EU Directive 2006/66/EC Batteries, FCC USA 47 CFR Part 15 DoC, China RoHS GB/T 26572-2011. The list of declarations of conformity is available on request sent to BESA GmbH.

Graefelfing, November, 15th 2021

Michael Kornwebel
Quality Manager
BESA GmbH