Kingsystems

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EU Declaration of Conformity

No.: REG-004062

We

Manufacturer:	King Systems
Single Registration number	[Currently not available]
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declare that the declaration is issued under the sole responsibility and belongs to the following devices:

Product name	Rigid Laryngoscope (King Vision aBlade Video Laryngoscope)
Intended purpose	The King Vision Video Laryngoscope is a rigid laryngoscope used to examine and visualize a patient's upper airway and aid in the placement of a tracheal tube.
Catalogue number(s)	KVIS01, KVIS01VA34, KVLABKIT3, KVLVA12, KVLVA34, KVLAB1, KVLAB2, KVLAB2C, KVLAB3 and KVLAB3C
Accessory	KVCABL - Video-Output Cable Note: The Display video-output may be connected to UL/IEC 60601-1 certified devices with a standard analog (RCA Style) port and NTSC video signal input, no additional peripheral devices shall be connected.
Device risk class	Class 1 (rule 5, Annex VIII)
Basic UDI-DI	570748030100530358B
GMDN code and term	43946, Rigid laryngopharyngoscope 46828, Laryngoscope blade, single use

European Representative:
Ambu A/S Baltorpbakken 13,2750 Ballerup, Denmark

The devices covered by the present declaration is in conformity with the requirements specified in the relevant Union legislation:
Medical Device Regulation 2017/745
Restriction of Hazardous Substances Directive (2011/65/EU)

Conformity assessment procedure:
Class I, non-sterile: Annex II and III

Signed for and behalf of King Systems:

Noblesville, IN USA — 04 Aug 2021 (Date) — Jason Dugger, Regulatory Affairs Manager

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