EC Declaration of Conformity

- Manufacturer

Shenzhen Coreray Technology Co., Ltd.
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SRN: CN-MF-000018015

- Authorized European Representative

EC REP

WellKang Ltd
Enterprise Hub, NW Business Complex, 1 Beraghmore Rd. Derry, BT48 8SE,
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SRN: XI-AR-000001836

- We, the manufacturer, hereby declare that the products as below meet the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical device. All supporting documentation is retained at the premises of the Manufacturer. The manufacturer is exclusively responsible for the declaration of conformity, which is applicable to the following products and valid until a revised declaration of conformity after product change and/or by the expiration date of the certificate.

Product Name	Model	EMDN code	Basic UDI-DI / GMN	Classification
Video Laryngoscope	CR-31	Z12021004 VIDEO LARYNGOSCOPES	69287378CR31WC	Class I (Rule 5, 10)
	CR-31D		69287378CR31DTB	
	CR-VLS-A		69287378CRVLSA6G	
	CR-VLS-P		69287378CRVLSP7E	

- Applied standards

EN ISO 13485: 2016, ISO 14971: 2019, IEC 60601-1:2005+A1:2012, IEC 60601-1-2:2015, ISO 10993-1: 2009, ISO 10993-5: 2009, ISO 10993-10: 2010, ISO 15223-1: 2021, EN 1041: 2008

- CE mark: CE

- Date CE mark was affixed: 08/26/2020 (M/D/Y).
- Issue by:

Simon Fan (General Manager)
Shenzhen, 12/13/2021 (M/D/Y)
Place, date

Coreray Technology Co., Ltd. 科瑞特医疗器械技术股份有限公司 Shenzhen

Legally binding signature