File No.: KRT-DC-31, A/2

EC Declaration of Conformity

■ Manufacturer



Shenzhen Coreray Technology Co., Ltd.

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SRN: CN-MF-000018015

■ Authorized European Representative



WellKang Ltd

Enterprise Hub, NW Business Complex, 1 Beraghmore Rd. Derry, BT48 8SE, Northern Ireland

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	Basic UDI-DI / GMN	GMDN code	Classification
Video Laryngoscope	CR-31 / CR-31D / CR-VLS	69287378CR3IWC	62761	Class I (Rule 5, 10)

■ 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: **(€**

- **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

