EC Declaration of Conformity

- Manufacturer

Shenzhen Coreray Technology Co., Ltd.
5F, Building 10, Huangbeiling Jingxuan Industrial Park, Yousong Community,
Longhua Street, Longhua District, Shenzhen, 518109, Guangdong, P.R. China
SRN: CN-MF-000018015

- Authorized European Representative

EC REP

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.

- Basic UDI-DI / GMN: 69287378CR001RM

Product Name	Model	EMDN code	Classification
SpO2 sensor	CR001 Series	Z1203020408 PULSE OXIMETERS	Class IIb (Rule 10)

- Applied standards

EN ISO 13485: 2016, ISO 14971: 2019, ISO 80601-2-61:2017, EN 60601-1:2006/A1:2013, EN 60601-1-2:2015, EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 10993-10: 2013, EN ISO 15223-1: 2016, EN 1041: 2008

- Notified Body

TÜV Rheinland LGA Products GmbH
Country: Germany
Notified Body number: 0197

- CE mark: CE 0197
- Date CE mark was affixed: 10/19/16 (M/D/Y).
- Issue by:

Simon Fan (General Manager)
Shenzhen, 12/13/21 (M/D/Y)
Place, date

Coreray Technology Co., Ltd. 科瑞特医疗器械有限公司 Shenzhen

Legally binding signature