Europe - EU declaration of conformity

According to Medical Device Directive. Classification: (MDD. Annex IX): II a, Rule 10

UMDNS CODE: 16173
GMDN CODE: 45617

Manufacturer:

Name:	CRESTA INTERNATIONAL B.V.
Address:	Rolbrugweg 4 – 1332 AS Almere The Netherlands

Equipment:

EAN number	8711974759505
Report reference	PG-800A32
Marketing name:	CRESTA CARE BPM220

Hereby, Cresta International BV declares that the above-mentioned products meet the provisions of the following EC council Directives and Standards and conformity with the Swedish legislation. All supporting documentations are retained under premises of the manufacturer and the notify body.

Directives:

Swedish legislation LVFS 2003:11

Medical Device Directive: Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD 83/42/EEC). Amended by Directive 2007/47/EC of 5 September 2007.

RoHS Directive (2011/65/EU)
REACH Directive (1907/2006/EC)

Standard:

All applicated harmonized Standards (published in the Official Journal of the European Communities)

Certificate:

41316438 Expiration date of the Certificate: 14 July 2023.
Date of the CE mark was affixed by:
Shenzhen Pango Electronics Co., LTD
No 25., 1ste Industry zone, Fenghuang Rd., Xikeng Village. Henggang Town. Longgang District. Shenzhen China.

Notified Body:

Intertek Semko AB
Box 1103, SE-164 22 Kista Sweden) code: 0413

EC REP
Authorised representatiove: Lotus NL B.V.
Konning Julianaplein 10, 2595AA The Hague, Netherlands
Tel: + 31 645171879

Supplementary information

The conformity to above standards is verified by the following 3rd party lab:
ACCURATE TECHNOLOGY CO., LTD
No 345., Baima Block, Guantai Road, Nancheng District, Dongguan, Guangdong China.

Certificate number: DGC160803003TE
Report no: DGC160803003TE

Signed for and on behalf of:	CRESTA INTERNATIONAL B.V.
Place:	Almere
Date:	January 4th, 2019
Name:	A. Benay
Title:	Director