IMAXEON

EC DECLARATION OF CONFORMITY

We: **With Our:**

Manufacturer	EC Authorized Representative
Imaxeon, Pty Ltd Unit 1 38-46 South St. Rydalmere, NSW 2116 Australia	Bayer Medical Care BV Avenue Céramique 27 6221 KV Maastricht The Netherlands

DECLARATION:

Imaxeon, Pty Ltd with sole responsibility declares that the above mentioned products meet all applicable requirements of the European Council Directive 93/42/EEC (as amended by 2007/47/EC) and 2006/42/EC including:

- Annex II, Clause 3 - EC DECLARATION OF CONFORMITY (Full Quality Assurance System)
- The essential health and safety requirements for Medical Devices in Annex I and applicable requirements of 2006/42/EC.

The below mentioned products:

- do not incorporate, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC;
- do not incorporate, as an integral part, a substance or a human blood derivative defined in Article 1(10) of 2001/83/EC;
- are not manufactured utilizing tissues of animal origin as referred to in Commission Directive 2003/32/EC (1);
- are in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment and have been demonstrated to meet the requirements specified in Article 4; and
- are in conformity with Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC Text with EEA relevance.

The quality system concerning the above mentioned product types has been evaluated by BSI (2797) utilizing the conformity assessment procedure identified in Annex II, Clause 3 of EU 93/42/EEC as amended by 2007/47/EC and certified on CE 623418 and MD 623422.

The CE marking has been affixed on the device according to article 17 of the EC Directive, 93/42/EEC as amended by 2007/47/EC.

This certificate is effective for the applicable manufactured products with the GTINs listed below as of the date of the signing of this certificate.

Anhua Hu
Regulatory Affairs Manager

Rydalmere, NSW, Australia
Place

April 23th, 2020
Date

IMAXEON

PRODUCT/PRODUCT FAMILY LIST INFORMATION

Catalog No.	Product	Risk Classification	GTIN
CENT-SYS-BAT	Centargo Pedestal System with Battery	Class IIb, Rule 11	9345390000430
CENT-SYS-PED	Centargo Pedestal System	Class IIb, Rule 11	9345390000423
CENT-P3T-CARD	Personalized Patient Protocol Technology (P3T) P3T Cardiac	Class IIb, Rule 11	NA - software
CENT-P3T-ABDO	Personalized Patient Protocol Technology (P3T) P3T Abdomen	Class IIb, Rule 11	NA - software
CENT-P3T-PULM	Personalized Patient Protocol Technology (P3T) P3T Pulmonary Angiography (PA)	Class IIb, Rule 11	NA - software
CENT-PAT	Protocol Assistant	Class IIb, Rule 11	NA - software
CENT-ISI-CCT	Connect.CT	Class IIb, Rule 11	NA - software