PLANER

UK/EU DECLARATION OF CONFORMITY

Product covered by this declaration
Controlled Rate Freezer System - Kryo300-M Series (Kryo360)

Manufacturer
Planer Limited. 110 Windmill Rd., Sunbury-on-Thames, Middlesex, TW16 7HD, UK.
This declaration of conformity is issued under the sole responsibility of the manufacturer .

Objects of this declaration
Model numbers:
KRYO360-1.7-M-230
GDKRYO360-1.7-M-230 1.7 litre Freezer System comprising
GDMRV-M (MRV Controller) & GDKRYO360CH-1.7-M-230 (1.7 litre Chamber)

KRYO360-1.7-M-230-02
GDKRYO360-1.7-M-230-02 1.7 litre Freezer System comprising
GDMR7 (MR7 Controller) & GDKRYO360CH-1.7-M-230 (1.7 litre Chamber)

KRYO360-3.3-M-230
GDKRYO360-3.3-M-230 3.3 litre Freezer System comprising
GDMRV-M (MRV Controller) & GDKRYO360CH-3.3-M-230 (3.3 litre Chamber)

KRYO360-3.3-M-230-02
GDKRYO360-3.3-M-230-02 3.3 litre Freezer System comprising
GDMR7 (MR7 Controller) & GDKRYO360CH-3.3-M-230 (3.3 litre Chamber)

The "GD" prefix is applied to the model number to create a catalogue number . The catalogue number is required for ordering purposes only. Numbers with or without the "GD" prefix relate the same Freezer System.

Intended Use Statement :	The Series 300 and 500 Medical Device models are specifically designed for users who need to cool or heat samples following a defined temperature -time profile, as part of patient treatment or diagnosis and where the samples will subsequently be re-introduced into the body.
EU Authorised Representative :	EC REP **Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta**

Serial numbers:

53825

GMDN code: 35829, 44622.Unique Device Identification(UDI): ++B199KRYOGS.

Statement of conformity	**The basis on which conformity is being declared**
The objects of the declaration described above are in conformity with the relevant Union harmonisation legislation listed below: 2014/30/EU EMC Directive 2011/65/EU RoHS Directive (EU) 2017/745 Medical Device Regulations S.I. 2016/1091 Electromagnetic Compatibility Regulations 2016 S.I. 2012/3032 RoHS Regulations 2012 S.I. 2002/618 Medical Devices Regulations 2002	The products identified above comply with the essential requirements of the above EU Directives by application of the following standards. BS EN 50581: 2012 BS EN 61010-1: 2010 BS EN 61326-1: 2013 BS EN 62304: 2006+A1:2015 BS EN 62366-1: 2015 BS EN ISO 13485: 2016 BS EN ISO 14971: 2012

Medical device additional information :
MDR Classification: Class I according to rule 1.

Signed for and on behalf of Planer Limited.

Name: Dave Barber/Planer	Signature: 

Position: Operations Director	Date: 23/06/2022 14:26:08

The attention of the specifier, purchaser, installer or user is drawn to special measures and limitations of use which must be observed when the product is taken into service to maintain compliance with the above directives . Details of these measures, if any, are given in the instructions supplied with the products .

The Technical Construction File is compiled the QA & Regulatory Affairs Manager; Planer Limited. 110 Windmill Rd., Sunbury-on-Thames, Middlesex, TW16 7HD, UK. The CE Mark was first applied in 28/02/2003 : document reference TCF-SBUR-5C6L6B rev 028