

# Certificate of Designation<sup>®</sup>

In accordance with Clause 2 of the Mandate executed by both the Legal Manufacturer and Advena Limited, this Certificate of Designation is issued and confirms the period of representation. Furthermore, this certificate confirms the medical devices Advena Limited acts as EU Authorised Representative for the Manufacturer.

<b>Client Reference:</b> GBR/2018/08/23	<b>Commencement Date:</b> 01 <sup>st</sup> November 2020	<b>Expiry Date:</b> 31 <sup>st</sup> October 2021
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<b>Legal Manufacturer</b>	<b>EU Authorised Representative (EC REP)</b>
<b>Planer Limited</b> 110 Windmill Road, Sunbury-on-Thames, Middlesex, TW16 7HD, UK	Advena Limited, Tower Business Centre, 2 <sup>nd</sup> Flr, Tower Street, Swatar, BKR 4013 Malta.

Product Details, Names or Trade Names (Taken from the Declaration of Conformity)	Device Classification	Date of Declaration
1.7 L and 3.3 L Chamber + MRV 230V Medical Device (Kryo360)	Class I	30 <sup>th</sup> November 2020
16L Chamber + MRV Controller freezing system. (Kryo560)	Class I	30 <sup>th</sup> November 2020
Integra 750Plus (Medical Device Version) (Integra 750Plus)	Class I	30 <sup>th</sup> November 2020
BT37 Bench-top incubator (BT37 Mark I (BT37-01) and BT37 Mark II (BT37-02))	Class IIa	01 <sup>st</sup> December 2020
CT37stax Medical Device Version (CT37stax)	Class IIa	30 <sup>th</sup> November 2020

The device labelling or packaging or the IFU for the above-named devices must indicate Advena as the EU Authorised Representative, and in the following format:

<b>EC</b>	<b>REP</b>	Advena Ltd. Tower Business Centre, 2 <sup>nd</sup> Flr., Tower Street, Swatar, BKR 4013 Malta
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<b>The Competent Authority in the territory which Advena Ltd provides its EU Authorised Representative service is as follows:</b>
<b>Malta Medicines Authority (MMA)</b> Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000 Malta. Tel: +356 2343 9000 Email: <a href="mailto:info.medicinesauthority@gov.mt">info.medicinesauthority@gov.mt</a>

<b>This certificate is issued by:</b>	<b>Authorised Signature:</b>
<b>Advena Limited</b> Tower Business Centre, 2 <sup>nd</sup> Flr, Tower Street, Swatar, BKR 4013. Malta. Tel: +44 1926 800153 Email: <a href="mailto:info@advenamedical.com">info@advenamedical.com</a> Registered in Malta No. C 76865	<i>A. Kirby</i> Anthony Kirby - Managing Director <sup>®</sup> (Malta)

This certificate is subject to the legal manufacturer maintaining their documentation in compliance with the relevant directive or regulation. Please refer to the executed mandate and declaration(s) of conformity for confirmation.

This certificate is for the exclusive use of Advena Ltd's client and is provided pursuant of the European Authorised Representative agreement (Mandate) between Advena Ltd and the client. Advena's responsibility and liability is limited to the terms and conditions of this agreement. Advena Ltd assumes no liability to any party for any loss, expense or damage occasioned by the use of this certificate and the European Authorised Representative agreement (Mandate). Only the client is authorised to copy or distribute this certificate. Any use of the Advena Ltd name by others who are not covered by the above agreement, or any similar contract, is prohibited. This certificate remains valid until the expiry date has been reached or has been terminated by Advena Limited.



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