EC Certificate Full Quality Assurance System: Certificate GB20/965317

The management system of

Planer Limited

110 Windmill Road, Sunbury-on-Thames, Middlesex, TW16 7HD, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Incubators intended for assisted reproductive technologies:

Incubators:
BT37 & CT37-M

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 21 May 2021 until 31 July 2023
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 28 February 2003

Certification is based on reports numbered GB/PC 240639

Authorised by

Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

Planer Limited
Windmill Road, 110
Sunbury-on-Thames,
TW16 7HD
UK

02/05/2023

Confirmation Letter Reference: CLNB1639 GBPC240639

To whom it may concern,

Confirmation of receipt of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Planer Limited
Windmill Road, 110
Sunbury-on-Thames,
TW16 7HD
UK

Eu rep:
Advena Ltd
Tower Business Centre, 2nd Flr,
Tower Street, Swatar, BKR 4013
Malta
SRN: MT-AR-000000234

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15 March 2023, this letter also confirms that:

- the manufacturer submitted the MDR application and signed the written agreement by the date of MDD certificate expiry 31/07/2023;
- the certificates expired after 26 May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body SGS Belgium NV 1639,

pp [Jérôme JADOT]

Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone : +41 22 739 98 58

Devices covered by this letter:

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Incubators intended for assisted reproductive technologies: Incubators: BT37	Class IIa	N/A	GB20/965317; NB1639

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Incubators intended for assisted reproductive technologies: Incubators: CT37-M	Class IIa	N/A	GB20/965317; NB1639

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/05/02	Version 1	Initial issue

PRESERVE / PROTECT / NURTURE

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TW16 7HD
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www.planer.com
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A Hamilton Thorne Group Company

Statement regarding the conditions of the MDD Extension

I, on behalf of Planer Limited, can confirm the following statements are, to the best of my knowledge, correct. The devices covered by this statement are:

- **BT37 Benchtop Incubator**
- **CT37stax Benchtop Incubator**

- The devices listed above remain in compliance with the Medical Device Directive 93/42/EEC,
- The devices listed above cannot be offered to the market with any significant changes to the design or intended use.
- The devices listed above do not constitute an unacceptable health and safety risk to patients, users, or others. There is no risk to public health.
- The Planer Quality Management system has already been audited against MDR (EU 2017/745) Article 10(9).
- Planer Limited has already applied to a notified body for the conformity assessment of the devices listed above to the MDR (EU 2017/745) Annex VII, art. 4.3, first sub-paragraph. A written agreement between Planer and our Notified Body has already been executed.
- The MDD extension granted to Planer expires 31st December 2028

Signed:

Name: Alan Boother
Position: Head of Quality & Regulatory Affairs (Person Responsible for Regulatory Compliance)
Email: aboother@planer.com
Date: 22nd June 2023