UKCA Certificate - Production Quality Assurance

Part II of The Medical Devices Regulations 2002, Annex V [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

No. **UKCA 782951**

Issued To: **Biotech, Inc.**
5975 Shiloh Rd.
Suite 101
Alpharetta
Georgia
30005
USA

In respect of:

Manufacture and final inspection of sterile assisted reproduction vitrification carriers.

On the basis of our examination of the quality assurance system under the requirements of Part II of the Medical Devices Regulations 2002, Annex V [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The quality assurance system meets the requirements of the regulation. For the placing on the market of class IIb and class III products an Annex III certificate (modified as described above) is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2023-05-17** Date: **2023-05-17** Expiry Date: **2027-11-08**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the regulation as demonstrated through the required surveillance activities of the Approved Body.
This certificate was issued electronically and is bound by the conditions of the contract.

Approved Body Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK. Tel: + 44 845 080 9000
Corporate Contact: BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London, W4 4AL, UK.
A member of BSI Group of Companies.

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Supplementary Information to UKCA 782951

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Device code	Device name	Intended purpose per IFU
Class IIa		
MD0109	Cryolock and S-Cryolock	---

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UKCA Certificate - Production Quality Assurance Certificate History

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Date: **2023-05-17**
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Date	Reference Number	Action
Current	3815057	First issue, traceable to MDR 755826

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