CERTIFICATE OF REGISTRATION

N° 34919–5

GMED certifies that the quality management system developed by

OriGen Biomedical, Inc.
7000 Burleson Road, Bldg. D
Austin UNITED STATES

Facility identifier (REPs-generated) : F000671

for the activities

Conception, Developpement, Fabrication et Distribution de sacs pour culture cellulaire, sacs de congélation et dispositifs associés de transfert de fluides et solutions de cryoconservation.

Design, development, manufacture and distribution of cell culture bags, freezing bags and associated fluid transfer devices and cryopreservation solutions.

performed on the location(s) of

OriGen Biomedical, Inc. 7000 Burleson Road, Bldg. D AUSTIN, TX 78744 USA

has been audited and found to conform to the requirements of the international standard ISO 13485 : 2016 and following regulatory requirements

Australia	Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil	RDC ANVISA n. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009
Canada	Medical Devices Regulations - Part 1 - SOR 98/282
Japan	MHLW MO 169 PMD Act
United States	21 CFR 820 21 CFR 803 21 CFR 806 21 CFR 807 - -Subparts A to D 21 CFR 821 (where applicable)

Début de validité */ Effective date* **August 31st, 2023 (included)**
Valable jusqu'au */ Expiry date :* **December 3rd, 2024 (included)**
Etabli le */ Issued on :* **August 31st, 2023**

GMED SAS GMED SAS GMED GROUPE LNE

DocuSigned by: Béatrice LYS EF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

GMED is authorised under the Medical Devices Single Audit Program
This certificate is issued according to the rules of GMED Certification
The validity of this certificate can be verified on www.gmed.fr

Modifie le certificat 34919-4

GMED_MDSAP2016-F-V0-07-