CERTIFICATE OF REGISTRATION

N° 34919–1

GMED certifies that the quality management system developed by

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

D.U.N.S. identification number :62-527-2232

for the activities

Conception, fabrication et distribution de sacs pour culture cellulaire, sacs de congélation, solutions de cryoconservation, solutions de lavage pulmonaire

Design, manufacture and distribution of bags for cell culture, freezing bags, cryopreservation solutions and lung lavage 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. 16/2013 RDC ANVISA n. 23/2012 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* **May 28th, 2020 (included)**
Valable jusqu'au */ Expiry date :***December 3rd, 2021 (included)**
Etabli le */ Issued on :* **May 28th, 2020**

On behalf of the President
Béatrice LYS
Technical Director

DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

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 34919-0

GMED_MDSAP2016-F-V0-07-