CERTIFICATE OF REGISTRATION

N° 34919–0

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, cathéters vasculaires, solutions de cryoconservation, solutions de lavage pulmonaire

Design, manufacture and distribution of bags for cell culture, freezing bags, vascular catheters, cryopreservation solutions, 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
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* **December 4th, 2018 (included)**

Valable jusqu'au */ Expiry date :***December 3rd, 2021 (included)**

Etabli le */ Issued on :* **December 4th, 2018**

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

GMED SAS GMED GROUPE LNE GMED SAS

Lionel DREUX
Certification Director

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