

*GMED certifies that the quality management system developed by*

**OriGen Biomedical, Inc.  
7000 Burleson Road, Bldg. D  
AUSTIN, TX 78744 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, solutions de cryoconservation et solutions de lavage pulmonaire.**

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

*performed on the location(s) of*

**OriGen Biomedical, Inc. 7000 Burleson Road, Bldg. D AUSTIN, TX 78744 USA  
OriGen Biomedical, Inc. 2301 E St. Elmo Rd. Bldg. 1, Ste 110, 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 April 12th, 2021 (included)**  
**Valable jusqu'au / Expiry date :December 3rd, 2021 (included)**  
**Etabli le / Issued on : April 12th, 2021**



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](http://www.gmed.fr)

Modifie le certificat 34919-1



DocuSigned by:  
*Beatrice Lys*  
 EF33BDA9BAA04A3...

**On behalf of the President  
 Béatrice LYS  
 Technical Director**

**Ce certificat couvre les activités et les sites suivants :**

*This certificate covers the following activities and sites:*

**OriGen Biomedical, Inc.**

7000 Burleson Road, Bldg. D,  
Austin, TX 78744 - USA

Conception, Développement, Fabrication et Distribution /  
*Design, Development, Manufacture, and Distribution*

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**OriGen Biomedical, Inc.**

2301 E St. Elmo Rd. Bldg. 1, Ste 110,  
Austin, TX 78744 - USA

Fabrication, Assemblage, Conditionnement, Contrôle qualité /  
*Manufacture, Assembly, Packaging, quality control*

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**2 sites / 2 sites**



DocuSigned by:  
*Beatrice Lys*  
EF33BDA9BAA04A3...

**On behalf of the President  
Béatrice LYS  
Technical Director**