

## **ATTESTATION CE / EC CERTIFICATE**

Approbation du Système Complet d'assurance Qualité/ Approval of full Quality Assurance System

**ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux**

*ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices*

**Pour les dispositifs de classe III, un certificat CE de conception est requis**

*For class III devices, a EC design certificate is required*

**Fabricant / Manufacturer**

**OriGen Biomedical, Inc.**

**7000 Burleson Road, Bldg. D**

**AUSTIN, TX 78744 UNITED STATES**

**Catégorie du(des) dispositif(s) / Device(s) category**

**Sacs de culture cellulaire, de congélation et dispositifs associés de transfert de fluides, solutions de cryoconservation.**

*Cell culture, freezing bags and associated fluids transfer devices, cryopreservation solutions*

Voir document complémentaire GMED / See GMED additional document

**n° 37206**

**GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé T001098, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.**

*GMED certifies that, on the basis of the results contained in the file referenced T001098, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4.*

La validité du présent certificat est soumise à une vérification périodique ou imprévue

The validity of the certificate is subject to periodic or unexpected verification

**Début de validité / Effective date : April 13th, 2021 (included)**

**Valable jusqu'au / Expiry date : May 26th, 2024 (included)**



DocuSigned by:

*Beatrice Lys*

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**On behalf of the President**

**Béatrice LYS**

**Technical Director**

**Ce document complémentaire GMED n° 37206 rev. 1 atteste de la validité du certificat CE n° 34262 rev. 6 au regard des informations listées ci-dessous.**

*This GMED additional document N° 37206 rev. 1 attests to the validity of CE certificate n° 34262 rev. 6 with regard to the information listed below.*

**Fabricant / Manufacturer: OriGen Biomedical, Inc.**  
**7000 Burleson Road, Bldg. D**  
**AUSTIN, TX 78744 UNITED STATES**

**Identification des dispositifs / Identification of devices**

Désignation du dispositif / Accessories marqués CE <i>Device designation / EC marked accessories</i>	Réf commerciale du dispositif ou code article <i>Device commercial reference or article code</i>	Classe du DM <i>MD Class</i>
CryoPur-D: 55% DMSO, 5% Dextran-40 w/v, Balance Sterile Water Sterile, Non Pyrogenic, Vial, 7.2ml filled volume	CD-07	Ila
CryoPur-D: 55% DMSO, 5% Dextran-40 w/v, Balance Sterile Water Sterile, Non Pyrogenic, Vial, 100ml filled volume	CD-100	Ila
CryoPur-D: 55% DMSO, 5% Dextran-40 w/v, Balance Sterile Water Sterile, Non Pyrogenic, Vial, 50ml filled volume	CD-50	Ila
DMSO/Dextran-40, 55% DMSO / 5% Dextran-40 in 0.9% saline, 100 ml fill volume	CDS-100A	Ila
CryoPur: 100% DMSO, 10ml filled volume	CP-10	Ila
CryoPur: 100% DMSO, 100ml filled volume	CP-100	Ila
CryoPur: 100% DMSO, 50ml filled volume	CP-50	Ila
CryoPur: 100% DMSO, 50ml filled volume	CP-50-T	Ila
CryoPur: 100% DMSO, Vial 70ml filled volume	CP-70	Ila
10ml syringe of 55% w/v DMSO, 5% w/v Dextran-40 in a sterile water solution w/ stopcock and 15cm of SCD tubing	SD-10	Ila
5ml syringe of 55% w/v DMSO, 5% w/v Dextran-40 in 0.9% saline solution, with 2ml of air in the syringe w/ stopcock and 15 cm of SCD tubing	SDS-05A-B	Ila
15ml syringe of 55% w/v DMSO, 5% w/v Dextran-40 in 0.9% saline solution w/ stopcock and 15cm of SCD tubing	SDS-15A-F	Ila
10ml syringe of 100% DMSO w/ stopcock and 15cm of SCD tubing	SP-10	Ila
20ml syringe of 100% DMSO w/ stopcock and 15cm of SCD tubing	SP-20	Ila
30ml syringe of 100% DMSO w/ stopcock and 15cm of SCD tubing	SP-30	Ila
50ml syringe of 100% DMSO w/ stopcock and 15cm of SCD tubing	SP-50	Ila
50 ml syringe of 100% DMSO w/ stopcock adhesive bonded to 15 cm of SCD tubing	SP-50-4	Ila

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**Technical Director**

<b>Désignation du dispositif / Accessoires marqués CE</b> <i>Device designation / EC marked accessories</i>	<b>Réf commerciale du dispositif ou code article</b> <i>Device commercial reference or article code</i>	<b>Classe du DM</b> <i>MD Class</i>
Needle-free vial spike, DMSO-resistant	VSV	Is
Set of 2 EVO Bags	KV3	Ila
TissueVault, Cell and Tissue Freezing 9x9cm bag	TV0909	Ila
TissueVault, Cell and Tissue Freezing 9x18cm bag	TV0918	Ila
TissueVault, Cell and Tissue Freezing 14x30cm bag	TV1430	Ila
TissueVault, Cell and Tissue Freezing 19x36cm bag	TV1936	Ila
TissueVault, Cell and Tissue Freezing 19x50cm bag	TV1950	Ila
TissueVault, Cell and Tissue Freezing 24x36cm bag	TV2436	Ila
O-Wrap 24x36cm pouch for LN freezing, packs of 5	OW 2436	Ila
O-Wrap, overwrap pouch for freezing, 4X19cm	OW0419	Ila
O-Wrap, overwrap pouch for freezing, 9x9cm	OW0909	Ila
O-Wrap, overwrap pouch for freezing, 9x18cm	OW0918	Ila
O-Wrap, overwrap pouch for freezing, 14x30cm	OW1430	Ila
O-Wrap overwrap 3-layer pouch for freezing, 14x30cm	OW1430T	Ila
O-Wrap, overwrap pouch for freezing, 19x36cm	OW1936	Ila
Cryostore 1000 EVA Freezing Bag, 120 - 275 ml, "N" Tubing Set	CS1000N	Ila
Cryostore 1000 EVA Freezing Bag, 120-275ml, "N" Tube Set, double aseptically packed	CS1000NS	Ila
Cryostore 1950 EVA Freezing Bag, 180-450ml, "Y8" Tube Set, double aseptically packed in OW	CS1950aY8SW	Ila
Cryostore 2000 EVA Freezing Bag, 180-450ml, "Y8" Tube Set, double aseptically packed in OW	CS2000aY8SW	Ila
Cryostore 2000 EVA Freezing Bag, 180 - 450 ml, "N" tube set	CS2000N	Ila
Cryostore 2000 EVA Freezing Bag, 180 - 450 ml, "N" tube set, singly packed	CS2000NP	Ila
Cryostore 2000 EVA Freezing Bag, 180-450ml, "N" Tube Set, double aseptically packed	CS2000NS	Ila
Cryostore EVA 4 Chamber Freezing Bag, 24 ml, "M9" Tube Set	CS24M9	Ila
Cryostore 250 EVA Freezing Bag, 30-70ml, "Standard" Tube Set	CS250	Ila
Cryostore 250 EVA Freezing Bag, 30-70ml, "F7" Tube Set	CS250F7	Ila
Cryostore 250 EVA Freezing Bag, 30-70ml, "N" Tube Set	CS250N	Ila
Cryostore 250 EVA Freezing Bag, 30-70ml, "N" Tube Set, double aseptically packed	CS250NS	Ila
Cryostore 250 EVA Freezing Bag, 30-70ml, "N" Tube Set, double aseptically packed in OW	CS250NSW	Ila
Cryostore 250 EVA Freezing Bag, 30-70ml, "Standard" Tube Set, double aseptically packed	CS250S	Ila
Cryostore 25 EVA Freezing Bag, 10-25ml, "F" Tube Set	CS25F	Ila
Cryostore 25 EVA Freezing Bag, 10-25ml, "F" Tube Set, singly packed	CS25FP	Ila
Cryostore 25 EVA Freezing Bag, 10-25ml, "N" Tube Set	CS25N	Ila
Cryostore 25 EVA Freezing Bag, 10-25ml, "N" Tube Set, double aseptically packed	CS25NS	Ila
Cryostore 25 EVA Freezing Bag, 10-25ml, "N" Tube Set, double aseptically packed in OW	CS25NSW	Ila

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Cryostore 25 EVA Freezing Bag, 10-25ml, "N" Tube Set, 8" donor tube	CS25XN	Ila
Cryostore 25 EVA Freezing Bag, 10-25ml, "Y4" Tube Set	CS25Y4	Ila
Cryostore 28 EVA Freezing Bag, 10-25ml, "V" Tube Set	CS28V	Ila
Cryostore 30 EVA Multi-Chamber Freezing Bag, 30ml, "M9" Tube Set	CS30M9	Ila
Cryostore 400 EVA Freezing Bag, 55-100ml, custom length 8 inches, "Standard" Tube Set	CS400	Ila
Cryostore 50 EVA Freezing Bag, 10-30ml, "Standard" Tube Set	CS50	Ila
Cryostore 500 EVA Freezing Bag, 55-100ml, "Standard" Tube Set	CS500	Ila
CS 500 EVA Bag, custom-width 10.9cm, "N" Tube set, in custom-width OW	CS500i2PW	Ila
Cryostore 500 EVA Freezing Bag, 55-100ml, custom length 7.5 inches, "Standard" Tube Set	CS500i3	Ila
Cryostore 500 EVA Freezing Bag, 55-100ml, "N" Tube Set	CS500N	Ila
Cryostore 500 EVA Freezing Bag, 55-100ml, "N" Tube Set, double aseptically packed	CS500NS	Ila
Cryostore 500 EVA Freezing Bag, 55-100ml, "N" Tube Set, double aseptically packed in OW	CS500NSW	Ila
Cryostore 500 EVA Freezing Bag, 55-100ml, "N" Tube Set, double aseptically packed in triple OW	CS500NSWT	Ila
Cryostore 500 EVA Freezing Bag, 55-100ml, "Standard" Tube Set, double aseptically packed	CS500S	Ila
Custom 500 EVA 2-Bag set with spikes, 55-100ml, "V2" Tube Set, 2 sets per pouch	CS500V2	Ila
CryoStore 500 EVA Freezing Bag, 8-bag set, 55-100ml, "V8" Tube Set	CS500V8	Ila
Cryostore 50 EVA Freezing Bag, 10-30ml, "M3" Tube Set	CS50M3	Ila
Cryostore 50 EVA Freezing Bag, 10-30ml, "N" Tube Set	CS50N	Ila
Cryostore 50 EVA Freezing Bag, 10-30ml, "N" Tube Set, double aseptically packed	CS50NS	Ila
Cryostore 50 EVA Freezing Bag, 10-30ml, "Standard" Tube Set, double aseptically packed	CS50S	Ila
CryoStore multiple bag set, ten 50 EVA freezing bags, 10- 30 ml, and one 750 EVA freezing bag, 80-190ml, "V7" Tube Set	CS50V7	Ila
Cryostore 750 EVA Freezing Bag, 80-190ml, "N" Tube Set	CS750N	Ila
Cryostore 750 EVA Freezing Bag, 80-190ml, "N" Tube Set, double aseptically packed	CS750NS	Ila
Cryostore 750 EVA Freezing Bag, 80-190ml, "N" Tube Set, double aseptically packed in OW	CS750NSW	Ila
Cryostore 750 EVA Freezing Bag, 80-190ml, "Standard" Tube Set	CS750	Ila
Cryostore 2500 Conical EVA Freezing Bag, 730-810ml, " Y14" Tube Set	CSD2500Y14	Ila
Cryostore 400 Conical EVA Freezing Bag 60-135ml, "Y9" Tube Set	CSD400Y9	Ila
3ml syringe on a female luer with 15cm of SCD tubing	15-R3FT	Ila
6 mL syringe with 5 mL of air on a female luer with 15cm sealed SCD tubing	15-R6F-TA	Ila

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12ml syringe on a female luer with 15cm sealed SCD tubing	15-RF12-T	Ila
20ml syringe on a female luer with 15cm sealed SCD tubing	15-RF20-T	Ila
60ml syringe on a female luer with 15cm sealed SCD tubing	15-RF60-T	Ila
20 cm sterile dockable sealed tube with a 0.22um filter and a 5um filter Single aseptic pouched.	20HAS	Ila
Three 12cm SCD tube leads to one 12cm SCD tube lead	24-T-3T	Ila
Two male luers to one female luer with 17cm of DMSO resistant tubing	2M-F17	Ila
Two spike ports to one spike with 16cm SCD tubing	2P-S16	Ila
Two spikes to one spike port with 20cm SCD tubing and pinch clamps	2S-P20	Ila
Two spikes to nine male luers with 140cm SCD tubing and pinch clamps	2S-9M141	Ila
Two male luers to one spike port and one female luer with 20cm SCD tubing with pinch clamps	40-PF-2M	Ila
One female luer to nine male luers with 45cm SCD tubing and pinch clamps	45-F-9M	Ila
Four spikes to four male luers with 60cm SCD tubing, roller and pinch clamps	4S-4M60	Ila
One 60ml syringe with one 0.22um filter and one 5um filter Single aseptically pouched	80HAS	Ila
DMSO resistant Bag Spike w/ Needle-Free Injection Port	CBS	Ila
Two spikes to a 3-way stopcock, 60ml syringe and needle-free valve to four male luers with 70cm SCD tubing and pinch clamps.	CC1	Ila
One spike and male luer to a 3-way stopcock, 60ml syringe and needle- free valve to four male luers with 70cm SCD tubing and pinch clamps.	CC2	Ila
One female luer to eight spikes with 100cm of SCD tubing and pinch clamps	F-8S100	Ila
DMSO-Resistant Bag Spike with needle injection port	IBS	Ila
Needle-free valve with cap	NFV	Ila
Protective Cap for Female Luer	PC2-B	Ila
3ml syringe on a female luer with 15cm sealed SCD tubing	R3F-T15	Ila
6ml syringe with a female luer with 15cm sealed SCD tubing	RF-T15	Ila
6ml syringe on a needle-free valve with 15cm SCD tubing with porous vent plug	RV-T15	Ila
60ml syringe on a needle-free valve with 15cm SCD tubing with porous vent plug	RV50-T15	Ila
One spike to one spike port and two female luers with 12cm SCD tubing and pinch clamps	S- FFP12	Ila
One spike to one 3/8" barb with 12cm DMSO resistant tubing	S-38B12	Ila
One spike to one female luer with 10cm DMSO resistant tubing and pinch clamp	S-F10	Ila
One spike to one female luer with 50cm of SCD tubing and pinch clamp	S-F50	Ila
One spike to one male luer with 10cm DMSO resistant tubing and pinch clamp	S-M10	Ila

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One spike to one male luer with 50cm SCD tubing and pinch clamp	S-M50	Ila
One spike to one spike with 50cm of SCD tubing and pinch clamp	S-S50	Ila
One spike to one male luer with 50cm SCD tubing and roller clamp	SU-M50	Ila
4-way stopcock, individually pouched	SC-1	Ila
PermaLife Cell Culture Bag, 7ml	PL07	Ila
PermaLife Cell Culture Bag, 7 mL - no green vent cap	PL07-2G	Ila
PermaLife Cell Culture Bag, 1000ml, "P" Set, packed with additional spike port	PL1000P	Ila
PermaLife Cell Culture Bag, 1000ml, "P" Set, packed with additional spike port - no green vent cap	PL1000P-2G	Ila
PermaLife Cell Culture Bag, 120ml	PL120	Ila
PermaLife Cell Culture Bag, 120 mL - no green vent cap	PL120-2G	Ila
PermaLife Cell Culture Bag, 120ml, with 10cm sheath	PL120M	Ila
PermaLife Cell Culture Bag, 120ml, with SCD tubing	PL120N	Ila
PermaLife Cell Culture Bag, 2000ml, "P2" Set, packed with additional NFV cover	PL2000P2-2G	Ila
PermaLife Cell Culture Bag, 240ml	PL240	Ila
PermaLife Cell Culture Bag, 240 mL - no green vent cap	PL240-2G	Ila
PermaLife Cell Culture Bag, 240ml, "K" Set	PL240K	Ila
PermaLife Cell Culture Bag, 30ml	PL30	Ila
PermaLife Cell Culture Bag, 30 mL - no green vent cap	PL30-2G	Ila
PermaLife Cell Culture Bag, 30ml with 10cm sheath	PL30M	Ila
PermaLife Cell Culture Bag, 325ml	PL325	Ila
PermaLife Cell Culture Bag, 325 mL - no green vent cap	PL325-2G	Ila
PermaLife Cell Culture Bag, 325ml, "K" set	PL325K	Ila
PermaLife Cell Culture Bag, 325ml with 10cm sheath	PL325M	Ila
PermaLife Cell Culture Bag, 325ml, with SCD tubing	PL325N	Ila
PermaLife Cell Culture Bag, 500 mL, "P" Set, packed with additional PVC spike port - no green vent cap	PL500P-2G	Ila
PermaLife Cell Culture Bag, 70ml	PL70	Ila
PermaLife Cell Culture Bag, 70 mL - no green vent cap	PL70-2G	Ila
PermaLife Cell Culture Bag, 750ml	PL750	Ila
PermaLife Cell Culture Bag, 750 mL - no green vent cap	PL750-2G	Ila
PermaLife Cell Culture Bag, 750ml, with SCD tubing	PL750N	Ila

### Sites couverts et Activités / Locations and Activities

Sites / Locations	Activités / Activities
<b>OriGen Biomedical, Inc.</b> 700 Burleson Road, Bldg. D Austin, TX 78744 USA	<b>Siège social, conception, fabrication et contrôle final</b> <i>Headquarters, design, manufacturing and final control</i>
<b>OriGen Biomedical, Inc.</b> 2301 E St. Elmo Rd. Bldg. 1, Ste 110 Austin, TX 78744 USA	<b>Fabrication</b> <i>Manufacturing</i>

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