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Date: May 28, 2024
Subject: OriGen's Transition from MDD to MDR
Products Affected: CryoStore Freezing Bags, Accessory Sets, PermaLife® Cell Culture Bags, O-Wrap® Bags, TissueVault™ Cell & Tissue Freezing Bags, CryoPur® Solutions

Dear Valued Customer,

The purpose of this communication is to detail OriGen Biomedical's transition from 93/42/EEC Medical Device Directive (MDD) to Regulation (EU) 2017/745 Medical Device Regulation (MDR). OriGen's MDD EC Certificate #34262 expired on May 26th, 2024. OriGen is actively transitioning to MDR, and the MDD CE certification dates have been extended as follows:

Product Family	MDD EC Certificate Expiration Date	MDD EC Certificate Extension Date
CryoStore Freezing Bags	May 26th, 2024	Dec 31st, 2028
Accessory Sets	May 26th, 2024	Dec 31st, 2028
PermaLife® Cell Culture Bags	May 26th, 2024	Dec 31st, 2028
O-Wrap® Bags	May 26th, 2024	Dec 31st, 2028
TissueVault™ Cell & Tissue Freezing Bags	May 26th, 2024	Dec 31st, 2028
CryoPur® Solutions	May 26th, 2024	Dec 31st, 2027

In conformance with Regulation (EU) 2023/607 amending Regulations (EU) 2017/745:

- OriGen's medical devices continue to comply with Directive 93/42/EEC (MDD);
- There have been no significant changes in the design and intended purpose;

- The devices do not present an unacceptable risk to the health or safety of patients, users, or other persons or to other aspects of the protection of public health;
- OriGen has an established Quality Management System in accordance with Article 10(9), reference ISO 13485 certificate # 34728;
- OriGen has lodged a formal application with GMED SAS (notified body #0459) in accordance with Regulation (EU) 2017/745 (MDR) Section 4.3, first subparagraph, of Annex VII for conformity assessment and has signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.

According to Regulation (EU) 2023/607 Article(1)(b)(3a), the Transitional provisions, Article 120 of Regulation (EU) 2017/745 (MDR) have been extended to December 31st 2027, for all class III devices and December 31st 2028, for class IIa devices.

MDD certificates will not be re-issued with these extended expiry dates, but the EU MDR has unilaterally extended the validity of current MDD certificates if specific criteria are met. OriGen Biomedical meets all required criteria for the transitional provisions.

For more information, please refer to the confirmation letter of extension (reference number 39724 rev. 0) from GMED SAS (notified body #0459). This letter confirms that GMED SAS, a Notified Body designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0459 on NANDO, has received a formal application for certification in accordance with Annex VII, section 4.3, first subparagraph, and has signed a written agreement (contract) in accordance with Annex VII, section 4.3, second paragraph of the said regulation with OriGen.

Additional Documentation:

- Manufacturer's Declaration
- Confirmation Letter of Extension from Notified Body
- EC Certificate 34262 (CE Mark Certificate)
- EC Certificate Addendum 37206 (CE Mark Certificate)

Please contact OriGen directly at info@origen.com if you have any additional questions. Thank you for your continued partnership.