

**CYTIVA TERMS AND CONDITIONS OF SALE FOR MEDICAL DEVICES**  
**(UNITED STATES, including PUERTO RICO)**  
**Revised as of October 2019.**

1. **IN ADDITION TO** applicable terms stated elsewhere, the following terms will apply to all purchases and other deliveries of Medical Devices from Cytiva Capitalized terms which are not defined here shall have the meaning given to them in the standard terms and conditions found at : <https://www.cytiva.com/terms>. These terms shall prevail over terms stated elsewhere where there is a conflict.

2. In these Terms and Conditions, **Medical Device** means any Product for which the U.S. Food and Drug Administration requires medical device registration. This includes, but is not limited to, Sepax™ 2 RM, Sepax 2 S-100, and Smart-Max™ and the protocols, accessories, kits and consumables marketed and sold for use with those products. A non-exhaustive list is provided below for convenience only.

*NOTE: these terms and conditions are not applicable to purchases of Contrast Media and Nuclear Imaging Agents.*

3. **Training.** Cytiva's training does not guarantee that: (i) Buyer trainees are fully trained on Medical Device use, maintenance or operation or (ii) training will satisfy any licensure or accreditation. Buyer must ensure its trainees are fully qualified in the use and operation of the Medical Device. Unless otherwise identified in the training catalogue, Buyer will complete training within 12 months after: (a) if with a Medical Device purchase, the date of Medical Device delivery; (b) if with a Services purchase, the start date for Services; or (c) if with a training-only purchase, the date training is ordered. If not done within this time period (other than because of Cytiva fault), training expires without refund.

4. **Medical Diagnosis and Treatment. All clinical and medical treatment, diagnostic and/or billing decisions are Buyer's sole responsibility.**

5. **Cost Reporting.** Buyer is aware of its legal obligations for **cost reporting**, including 42 C.F.R. § 1001.952(g) and (h), and will request from Cytiva the information beyond the invoice necessary to fulfill Buyer's cost reporting obligations.

6. **FAR.** Cytiva does not agree to any federal acquisition regulations ("FAR") unless specifically stated in a signed writing by Cytiva. Cytiva will provide safety-related Medical Device, including medical device Software, updates required by applicable laws and regulations at no additional charge.

7. **Warranty Limitations.** Any warranty granted by Cytiva with respect to the Medical Devices shall be deemed void if Buyer uses the Medical Device for non-medical or entertainment use, or outside the country of delivery. All warranties are automatically void if Buyer transfers or sells the Medical Device to any third party without Cytiva's prior written consent.

8. **Protected Health Information.** If Cytiva creates, receives, maintains, transmits or otherwise has access to Protected Health Information as such term is defined in 45 C.F.R. § 160.103 ("PHI"), it will only use and disclose the PHI as permitted by law and by the Business Associate Agreement between the parties.

9. **Data Rights.** Cytiva and its subcontractors may collect, prepare derivatives from and otherwise use non-PHI (personal health information) data related to Products, Services and/or SaaS for such things as training, demonstration, research, development, benchmarking, continuous improvement and facilitating the provision of its products, software and services. Cytiva will own all intellectual property and other rights that could result from this collection, preparation and use. The non-PHI data will not be used to identify Buyer or sold by Cytiva without Buyer's consent.. Cytiva shall at all times comply with all laws and regulations applicable to the use of, access to and confidentiality of data.

10. **VPN Security.** Buyer must provide a VPN or equivalent should remote support be requested. Buyer is responsible for maintaining security of such VPN.

11. **Excluded Provider.** To its knowledge, neither Cytiva nor its employees performing Services under this Agreement have been excluded from participation in a Federal Healthcare Program. If an employee performing Services under this Agreement is excluded, Cytiva will replace that employee within a reasonable time; if Cytiva is excluded, Buyer may terminate this Agreement upon written notice to Cytiva.

**12. Non-Exhaustive List of Medical Devices.**

- Biosafe labels , BioArchive compatible
- CordWash Sepax 2 protocol software
- Cryo-SC Smart-Max protocol software
- Sepax cell separation kit(s)
- Smart-Max cryopreparation accessory
- CryoSC-Db Freezing Bag
- NeatCell Sepax 2 protocol software
- Overwrap bag
- PeriCell Sepax 2 protocol software
- Seal Positioner b cryoSC-Db
- Separation chamber holder
- Sepax 2 RM
- Sepax 2 RM - Immobilisation
- Sepax 2 S-100
- Smart-Max AS-310
- SmartRedux Sepax 2 protocol software
- SmartWash Sepax 2 protocol software
- Traceability label for Cryopreservation
- UCB Sepax 2 protocol software
- AK-100
- AK-101
- FA-200.1

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