



Miltenyi Biotec

TexMACS™ GMP Medium

2000 mL bag

Order no. 170-076-306

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1. Description

Components	2000 mL TexMACS™ GMP Medium UV protection bag (yellow)
Main components	Salts, amino acids, vitamins, buffers.
Human Proteins	Contains human albumin (pharmaceutical grade).
Specifications	Osmolality: 280–340 mOsmol/kg pH: 6.9–7.3 Endotoxin: ≤0.5 EU/mL (Pharmacopoeia Europaea (Ph. Eur.)) Functionality assay: <i>Ex vivo</i> expansion of human T cells. Appearance: clear
Sterility	The medium is 0.1 µm filtered. Sterility is tested according to Ph. Eur. and USP.
Transport	At room temperature
Storage	Store TexMACS GMP Medium protected from light at +2 °C to +8 °C (+36 °F to +46 °F). Do not freeze.
Shelf life	The use-by date is indicated on the bag label.

Disclaimer

MACS GMP Products are for *ex vivo* cell processing only, and are not intended for human *in vivo* applications. For regulatory status in the USA, please contact your local representative.

Quality statement

MACS GMP Products are manufactured and tested under a quality management system (ISO 13485) and are in compliance with relevant GMP guidelines. They are designed following the recommendations of USP <1043> on ancillary materials. The manufacturing and testing of this product is compliant with the requirements laid down in the Ph.Eur. Chapter 5.2.12, if applicable.

The declaration of animal- or human-derived materials is given on the Certificate of Origin.

2. Applications

- TexMACS GMP Medium has been developed for the cultivation and expansion of human T cells and optimized for the use in combination with the CliniMACS® Cytokine Capture System (IFN-gamma).

3. Warnings and precautions

- ▲ The instructions for use must be followed.
- ▲ Do not inject or infuse the product directly into humans. Not for human application.
- ▲ When using this product, the national legislation and regulations must be followed. Any application of *ex vivo* processed target cells is exclusively within the responsibility of the user.
- ▲ For single use only. Do not reuse.
- ▲ Use undamaged bags only.
- ▲ Do not use after the use-by date indicated on the label.

4. Instructions for use

TexMACS GMP Medium filled in bags can be supplemented, for example, with cytokines or growth factors. Injection and sampling ports, including female luer locks and a tube for sterile welding maintain an aseptic workflow, to allow easy and convenient sampling.

- ▲ Cultures should be maintained protected from light at +37 °C (+99 °F) in a 5% CO₂ atmosphere.
- ▲ Optional: To protect TexMACS GMP Medium in bags from adverse effects caused by UV light, a UV protection bag (yellow) is provided with the 2 L TexMACS GMP Medium bag.

When using the TexMACS Medium bag under the influence of light (UV light) insert the bag in the provided yellow

protection bag. Carefully pass the tubing and connectors through the whole on the bottom of the bag. Turn over the upper edge of the protection bag in a way that the openings are placed on top of each other to enable hanging up the protected medium bag onto the Prodigy or other holder.

- ▲ For additional technical information, such as product quality certificate (PQC), please visit our website at www.macsgmp.com/certificates.

5. Glossary of symbols

	Manufacturer		Use-by date
	Order number		Phone
	Part number		Fax
	Batch code		E-mail
	Consult instruction for use		Website
	Do not use if package is damaged.		Protect from sunlight

This data sheet and corresponding information as well as special protocols can be found under www.miltenyibiotec.com/170-076-306.

Warranty

The products sold hereunder are warranted only to be free from defects in workmanship and material at the time of delivery to the customer. Miltenyi Biotec B.V. & Co. KG makes no warranty or representation, either expressed or implied, with respect to the fitness of a product for a particular purpose. There are no warranties, expressed or implied, which extend beyond the technical specifications of the products. Miltenyi Biotec B.V. & Co. KG's liability is limited to either replacement of the products or refund of the purchase price. Miltenyi Biotec B.V. & Co. KG is not liable for any property damage, personal injury or economic loss caused by the product.

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