Miltenyi Biotec

MACS® GMP Tyto® Consumables

GMP-compliant cell sorting with the MACSQuant® Tyto System



New possibilities in translational settings

Miltenyi Biotec is the first company worldwide to offer sterile, GMP-compliant multiparametric cell sorting in a fully closed setup. MACS® GMP Tyto® Consumables were specifically developed to enable cell sorting within GMP manufacturing environments using the MACSQuant® Tyto® System. As the microchip-based sorting process takes place exclusively within a fully closed and disposable cartridge, this opens up entirely new possibilities in translational and clinical research settings.





Sterile and safe

Cell sorting on the MACSQuant Tyto happens exclusively within the MACSQuant Tyto Cartridge. Inside this closed system, cells are protected from environmental contamination and remain sterile. Our MACS GMP Tyto Consumables were specifically developed for GMP-compliant cell sorting, facilitating translation into clinical research settings.

The transfer of sorting protocols between research use only (RUO) and GMP-compliant settings is easy as the basic sorting principle does not change. This allows for flexibility in the implementation and translation of newly developed applications.

Cells sorted on the MACSQuant Tyto remain inside the closed cartridge at all times during the sort process. Since there is no sheath fluid present within the system, the only materials that cells come in direct contact with are the following MACS GMP Products:

- MACS GMP Tyto Cartridge
- MACS GMP Tyto Running Buffer composed of:
  - MACS GMP PBS/$MgCl_2$ Buffer
  - MACS GMP Tytonase (20× stock solution)
- Optional: MACS GMP Fluorescent Antibodies for GMP-compliant cell labeling

VISIT

For more information on MACS GMP Fluorescent Antibodies and a complete list of products, visit

▸ **miltenyibiotec.com/GMPantibodies**

GMP-compliant cell sorting



Product-specific documentation for regulatory support

In addition to being subjected to extensive quality assurance and quality control measures, MACS® GMP Products come with a wide range of detailed documentation to support your regulatory filings.

- Batch-specific **Certificate of Analysis (CoA)**
- **Certificate of Origin (CoO)/TSE** (transmissible spongiform encephalopathies)
- **Product Information File (PIF)**
  - Description of the products (e.g. regulatory information, raw materials)
  - Specifications (e.g. in-process control, QC release testing)
  - Safety information (e.g. sterility, biocompatibility, endotoxins, particles)

Highest standards

- **Lot-to-lot consistency:** No time-consuming re-evaluation needed.
- **Regulatory support:** Facilitates discussions with your regulatory authorities.
- **Extensive stability studies:** Rely on consistent stability of the products.

MACS® GMP Quality

The success of your cell-based and gene therapy products for clinical research depends on the quality of the raw materials. Consistent high-quality products are essential for reliable and functionally relevant results.

As an experienced provider of products for regenerative medicine and tools for cell therapy applications, Miltenyi Biotec caters to customers' needs by providing the required technical and regulatory support.

MACS GMP PBS/$MgCl_2$ Buffer, MACS GMP Tytonase (20× stock solution) and the MACS GMP Tyto Cartridge are manufactured and tested according to a quality management system (ISO 13485). They are compliant with relevant GMP guidelines and designed following the recommendations of USP <1043> on ancillary materials. No animal- or human-derived materials are used for the manufacture of these products, unless otherwise stated in the respective Certificate of Origin. MACS GMP Products are for research use and *ex vivo* cell culture processing only, and are not intended for human *in vivo* applications.

MACS GMP Tyto Consumables	Order no.
MACS GMP Tyto Cartridge	170-076-011
MACS GMP PBS/$MgCl_2$ Buffer	170-076-155
MACS GMP Tytonase (20× stock solution)	170-076-210

▸ miltenyibiotec.com/GMPsorting

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In the EU, the CliniMACS System components are available as CE-marked medical devices for their respective intended use, unless otherwise stated. The CliniMACS Reagents and Biotin Conjugates are intended for *in vitro* use only and are not designated for therapeutic use or direct infusion into patients. The CliniMACS Reagents in combination with the CliniMACS System are intended to separate human cells. Miltenyi Biotec as the manufacturer of the CliniMACS System does not give any recommendations regarding the use of separated cells for therapeutic purposes and does not make any claims regarding a clinical benefit. For the manufacturing and use of target cells in humans the national legislation and regulations – e.g. for the EU the Directive 2004/23/EC ("human tissues and cells"), or the Directive 2002/98/EC ("human blood and blood components") – must be followed. Thus, any clinical application of the target cells is exclusively within the responsibility of the user of a CliniMACS System. In the US, the CliniMACS CD34 Reagent System, including the CliniMACS Plus Instrument, CliniMACS CD34 Reagent, CliniMACS Tubing Sets TS and LS, and the CliniMACS PBS/EDTA Buffer, is FDA approved as a Humanitarian Use Device (HUD), authorized by U.S. Federal law for use in the treatment of patients with acute myeloid leukemia (AML) in first complete remission. The effectiveness of the device for this indication has not been demonstrated. Other products of the CliniMACS Product Line are available for use only under an approved Investigational New Drug (IND) application, Investigational Device Exemption (IDE), or FDA approval. CliniMACS GMP MicroBeads are for research use and *ex vivo* cell processing only. CliniMACS MicroBeads are for research use only and not for human therapeutic or diagnostic use. CliniMACS, CliniMACS Prodigy, MACS, the Miltenyi Biotec logo, MACSQuant, and Tyto are registered trademarks or trademarks of Miltenyi Biotec and/or its affiliates in various countries worldwide. Copyright © 2021 Miltenyi Biotec and/or its affiliates. All rights reserved.

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