



Miltenyi Biotec

# MACS<sup>®</sup> GMP Tyto<sup>®</sup> Consumables

GMP-compliant cell sorting with the MACSQuant<sup>®</sup> Tyto System



**JOIN THE  
FLOW  
REVOLUTION**

# 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<sub>2</sub> Buffer
  - MACS GMP Tytonase (20x stock solution)
- Optional: MACS GMP Fluorescent Antibodies for GMP-compliant cell labeling

For more information on MACS GMP Fluorescent Antibodies and a complete list of products, visit [www.miltenyibiotec.com/GMPantibodies](http://www.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<sub>2</sub> Buffer, MACS GMP Tytonase (20x 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 <sub>2</sub> Buffer	170-076-155
MACS GMP Tytonase (20x stock solution)	170-076-210



## Miltenyi Biotec

### Germany/Austria

Miltenyi Biotec GmbH  
Friedrich-Ebert-Straße 68  
51429 Bergisch Gladbach  
Germany  
Phone +49 2204 8306-0  
Fax +49 2204 85197  
macs@miltenyibiotec.de

### USA/Canada

Miltenyi Biotec Inc.  
2303 Lindbergh Street  
Auburn, CA 95602, USA  
Phone 800 FOR MACS  
Phone +1 530 888 8871  
Fax +1 877 591 1060  
macs@miltenyibiotec.com

### Australia

Miltenyi Biotec  
Australia Pty. Ltd.  
Unit 16A, 2 Eden Park Drive  
Macquarie Park NSW 2113  
Australia  
Phone +61 2 8877 7400  
Fax +61 2 9889 5044  
macs@miltenyibiotec.com.au

### Benelux

Miltenyi Biotec B.V.  
Sandifortdreef 17  
2333 ZZ Leiden  
The Netherlands  
macs@miltenyibiotec.nl  
**Customer service  
The Netherlands**  
Phone 0800 4020120  
Fax 0800 4020100

### Customer service Belgium

Phone 0800 94016  
Fax 0800 99626

### Customer service Luxembourg

Phone 800 24971  
Fax 800 24984

### China

Miltenyi Biotec Technology &  
Trading (Shanghai) Co., Ltd.  
Rooms 2303 and 2309  
No. 319, Xianxia Road  
Changning District  
200051 Shanghai, P.R. China  
Phone +86 21 62351005  
Fax +86 21 62350953  
macs@miltenyibiotec.com.cn

### France

Miltenyi Biotec SAS  
10 rue Mercoeur  
75011 Paris, France  
Phone +33 1 56 98 16 16  
Fax +33 1 56 98 16 17  
macs@miltenyibiotec.fr

### Italy

Miltenyi Biotec S.r.l.  
Via Paolo Nanni Costa, 30  
40133 Bologna  
Italy  
Phone +39 051 6 460 411  
Fax +39 051 6 460 499  
macs@miltenyibiotec.it

### Japan

Miltenyi Biotec K.K.  
Nittsu-Eitai Building 5F  
16-10 Fuyuki, Koto-ku,  
Tokyo 135-0041, Japan  
Phone +81 3 5646 8910  
Fax +81 3 5646 8911  
macs@miltenyibiotec.jp

### Nordics and Baltics

Miltenyi Biotec Norden AB  
Scheelevägen 17  
223 70 Lund  
Sweden  
macs@miltenyibiotec.se  
**Customer service Sweden**  
Phone 0200-111 800  
Fax 046-280 72 99

### Customer service Denmark

Phone 80 20 30 10  
Fax +46 46 280 72 99

### Customer service

**Norway, Finland, Iceland,  
and Baltic countries**

Phone +46 46 280 72 80  
Fax +46 46 280 72 99

### Singapore

Miltenyi Biotec Asia Pacific Pte Ltd.  
100 Beach Road  
#28-06 to 28-08 Shaw Tower  
Singapore 189702  
Phone +65 6238 8183  
Fax +65 6238 0302  
macs@miltenyibiotec.com.sg

### South Korea

Miltenyi Biotec Korea Co., Ltd  
Arigi Bldg. 8F  
562 Nonhyeon-ro  
Gangnam-gu  
Seoul 06136, South Korea  
Phone +82 2 555 1988  
Fax +82 2 555 8890  
macs@miltenyibiotec.co.kr

### Spain

Miltenyi Biotec S.L.  
C/Luis Buñuel 2  
Ciudad de la Imagen  
28223 Pozuelo de Alarcón (Madrid)  
Spain  
Phone +34 91 512 12 90  
Fax +34 91 512 12 91  
macs@miltenyibiotec.es

### Switzerland

Miltenyi Biotec Swiss AG  
Gibelinstrasse 27  
4500 Solothurn  
Switzerland  
Phone +41 32 623 08 47  
Fax +49 2204 85197  
macs@miltenyibiotec.ch

### United Kingdom

Miltenyi Biotec Ltd.  
Almac House, Church Lane  
Bisley, Surrey GU24 9DR, UK  
Phone +44 1483 799 800  
Fax +44 1483 799 811  
macs@miltenyibiotec.co.uk

[www.miltenyibiotec.com](http://www.miltenyibiotec.com)

Miltenyi Biotec provides products and services worldwide. Visit [www.miltenyibiotec.com/local](http://www.miltenyibiotec.com/local) to find your nearest Miltenyi Biotec contact.

Unless otherwise specifically indicated, Miltenyi Biotec products and services are for research use only and not for therapeutic or diagnostic use. MACS® GMP Products are for research use and *ex vivo* cell culture processing only, and are not intended for human *in vivo* applications. For regulatory status in the USA, please contact your local representative. MACS GMP Products are manufactured and tested under a quality system certified to ISO 13485 and are in compliance with relevant GMP guidelines. They are designed following the recommendations of USP <1043> on ancillary materials. The CliniMACS® System components, including Reagents, Tubing Sets, Instruments, and PBS/EDTA Buffer, are designed, manufactured and tested under a quality system certified to ISO 13485. 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, products of the CliniMACS Product Line are available for use only under an approved Investigational New Drug (IND) application or Investigational Device Exemption (IDE). CliniMACS MicroBeads are for research use only and not for human therapeutic or diagnostic use. CliniMACS, CliniMACS Prodigy, MACS, the MACS logo, MACSQuant, and Tyto are registered trademarks or trademarks of Miltenyi Biotec GmbH and/or its affiliates in various countries worldwide. Copyright © 2019 Miltenyi Biotec GmbH and/or its affiliates. All rights reserved.