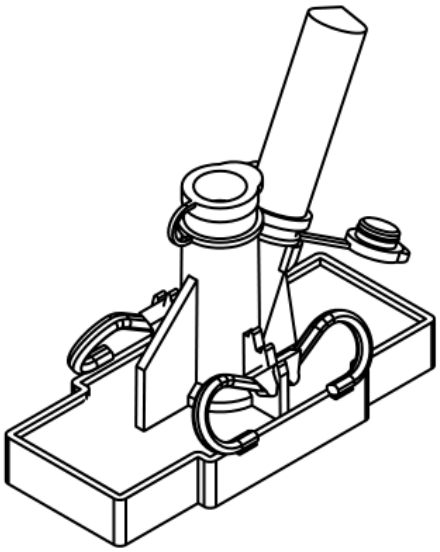
20610.EN rev.6

USER MANUAL



CYTO set

Read before use!

CE IVD

This manual was prepared with special care. MPW MED. INSTRUMENTS may change the manual at any time and without notice because of improvements, typographical errors or improvements to facilities

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Contents

1. Safety

Before starting work, familiarize yourself with this manual. Do not proceed to work before carefully reading all procedures described in this document and always follow the recommendations and markings contained in it. In case of doubt, please contact the manufacturer.

The product is intended for single use.

The shelf life of the CYTO set is 24 months from the date of purchase.

2. Destination

The CYTO set is a medical device equipment for in vitro diagnosis - a laboratory centrifuge specifically intended by the manufacturer for in vitro diagnostic (IVD) procedures within the meaning of Regulation (EU) 2017/746 of the European Parliament and of the Council of April 5, 2017 on medical devices for in vitro diagnosis and repealing Directive 98/79/EC and Commission Decision 2010/227/EU. The set is used for the preparation and storage of biological fluids intended for further in vitro diagnostics.

3. Technical specification

Product name	CYTO set
Cat. No (ref)	16610
Capacity	4x2ml
Max. Speed (rpm)	2500
G-force (RCF)	769 x g
Compatible rotor	12452C the rotor can be used in centrifuges : ▪ MPW M-DIAGNOSTIC, ▪ MPW-352, ▪ MPW-352R, ▪ MPW-352RH
Manufacturer	"MPW MED. INSTRUMENTS" SPÓŁDZIELNIA PRACY, Boremlowska 46 Street, 04-347 Warsaw

4. Principle of operation

CYTO set is designed to obtain an even cell preparation. Under the influence of centrifugal force, the morphotic elements (cell sediment) separate from the suspension and are deposited on the microscope slide. This solution is used in medicine and veterinary medicine, as well as widely in biology, biochemistry, cytology and histopathology. During one centrifugation cycle it is possible to obtain 4 preparations (using 4 sets).

There are two variants of obtaining the preparation:

a) **with obtaining the supernatant** - the supernatant is drained to a collection tube and can be used in subsequent diagnostic procedures,

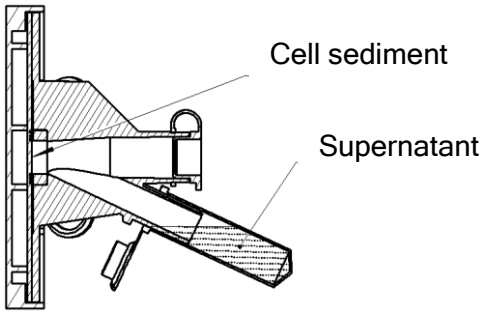

Figure 1 Cross-section of the CYTO set in the case of obtaining the preparation with obtaining the supernatant

b) **without obtaining the supernatant** - the supernatant is absorbed by the filter paper.

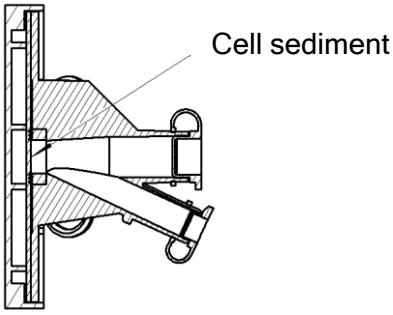

Figure 2 Cross-section of the CYTO set in the case of obtaining the preparation without obtaining supernatant

5. Components

Cat. no (REF)	No	Component name	pieces
16611	1	support	100
	2	overlay	100
	2a	central plug	100
	2b	side plug	100
16614	3	microscope slide	100
16116	4	filter paper with ø 9,5 mm hole	100
16617	5	filter paper with ø 12,5 mm hole	100
15123	6	supernatant tube 2,2ml with cup (pp)	100
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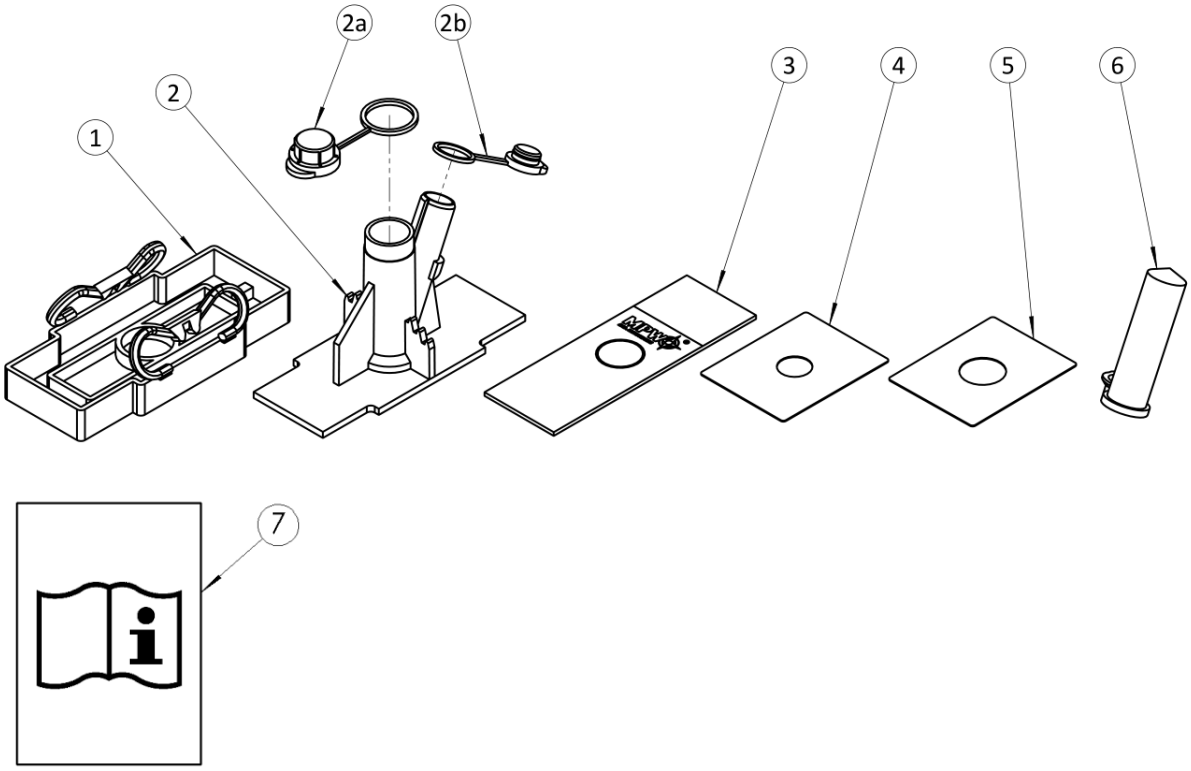

Figure 3 Ingredients provided

6. Obtaining the preparation with obtaining the supernatant

6.1. Rotor preparation

- Prepare the centrifuge for operation in accordance with recommendations contained in the centrifuge manual, and the rotor according to the following guidelines.
- Place hangers in the rotor so that the hook **A** is on the side of the **B** slider.

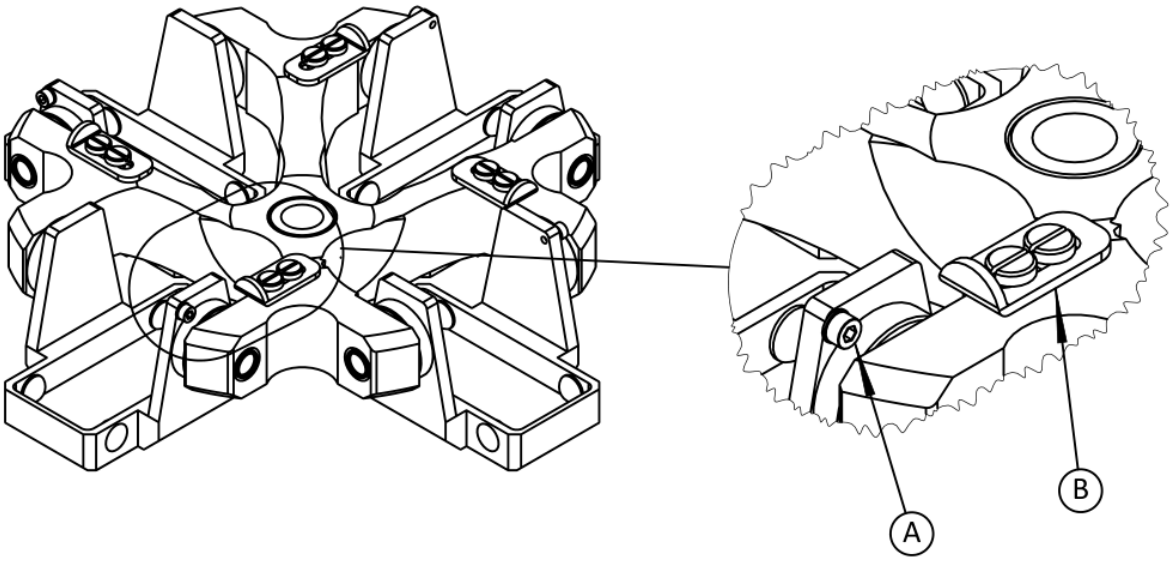

Figure 4. Placing hangers in the rotor

6.2. Initial centrifuging

- In order to improve the adhesion of cells to the microscope slide, it is recommended to lay them with phytolysin. The prepared and described microscope slide should be placed in the support (manufacturer's mark pointing upwards).
- Place a filter paper with a **Ø 12,5 mm** hole on the slide.
- Place the cover in the stand and fasten the buckles evenly.
- Pour the prepared liquid sample (max. 2 ml) into the central cylindrical hole of the CYTO set (marked with a dash) and then plug the hole with the cup.
- Place the supernatant tube on the sink cylinder hole of the CYTO set.

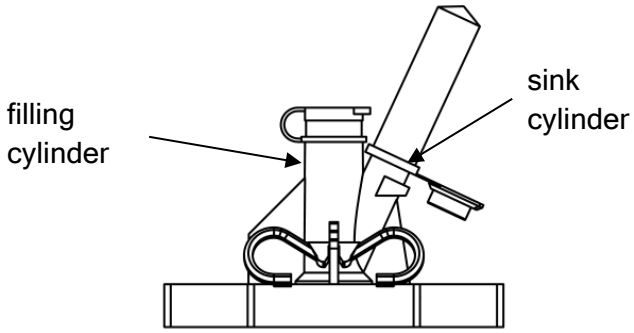

Figure 5. Set prepared for pre-centrifugation to obtain the supernatant

- Insert the CYTO sets (**4** or **2** in opposite sockets) into the hangers in the direction of the sink cylinders towards the rotor axis.

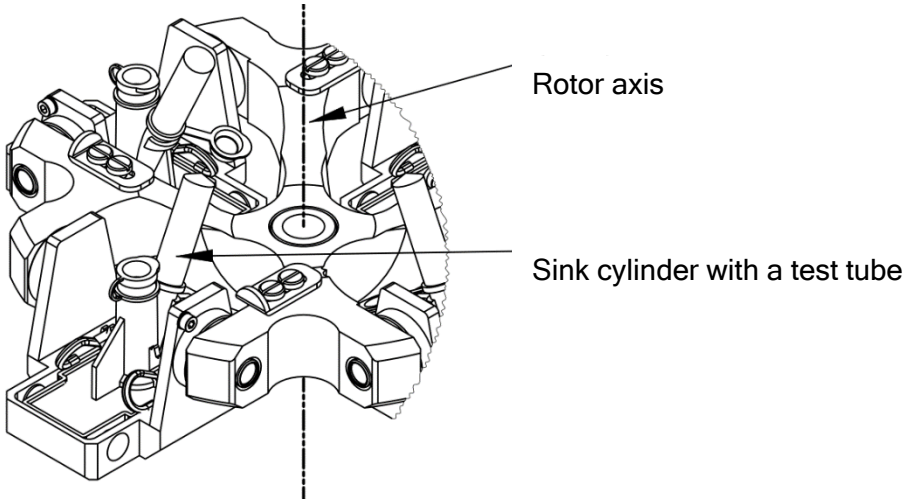

Figure 6 Placement of CYTO sets in the rotor

- Close the centrifuge lid.
- Set the spin speed and time.

Suggested spin parameters:

Spin speed	Time
1100 ÷ 1500 rpm	5 min

ATTENTION:
For **MPW-352, MPW-352R, MPW-352RH** centrifuges manufactured **up to 2018** (with serial numbers SN[1] up to 10352067918; 10352R050718; 10352RH009018) and **M-DIAGNOSTIC** produced **up to 2019** (serial no. SN up to 102MD011519) select the **acceleration characteristics with no. 3** (ACC) **and braking no. 6** (DEC).

- Start centrifuging.
- After centrifuging, open the centrifuge lid.

6.3. Drying centrifugation

- Remove the CYTO set from the rotor hanger, keeping its **vertical position**, so that the supernatant was always in the drain tube.
- With a gentle twisting motion, remove the test tube (containing the supernatant) and close it with the stopper. Close the drain hole of the insert with the plug.

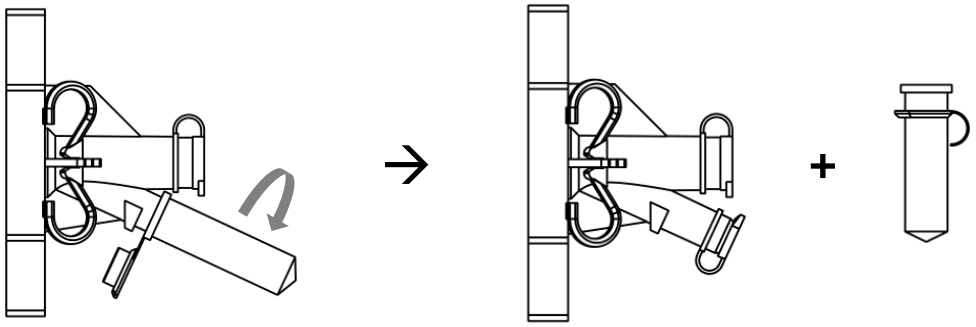

Figure 7 Set after preliminary centrifugation in the variant with obtaining the supernatant

[1] e.g., 10352067918, where 10352 stands for the symbol of the centrifuge, 0679 for the copy number, and 18 for the year of manufacture.

- After removing the test tube, put the set on one-side foil paper and remove the clips from the holders. Then, in the place indicated by the arrow, gently press to lift the cap together with the microscope slide.

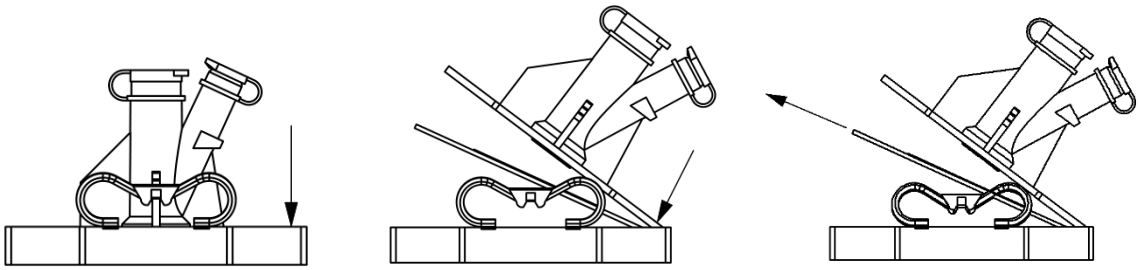

Figure 8 How to remove a microscope slide

- Carefully remove the slide, and then remove the tissue paper from the slide with the tweezers or tweezers.
- Place a **Ø 9.5 mm** blotting paper on the slide, trying not to disturb the specimen drop remaining on it. Then, place the slide with the applied filter paper together with the overlay in the holder and fasten the clasps evenly.
- Carry out a **drying centrifugation** at the same speed as in the previous process. The preparation will be partially dried.
- After centrifuging, remove the microscope slide again and use tweezers or tweezers to remove the filter paper. Fix the preparation and color it with selected techniques

7. Preparation without obtaining supernatant

7.1. Rotor preparation

- Prepare the centrifuge for operation in accordance with recommendations contained in the centrifuge manual, and the rotor according to the following guidelines.
- Place the hangers in the rotor in such a way that the hook **A** is next to the arm without the slider **C** (unlike the supernatant method).

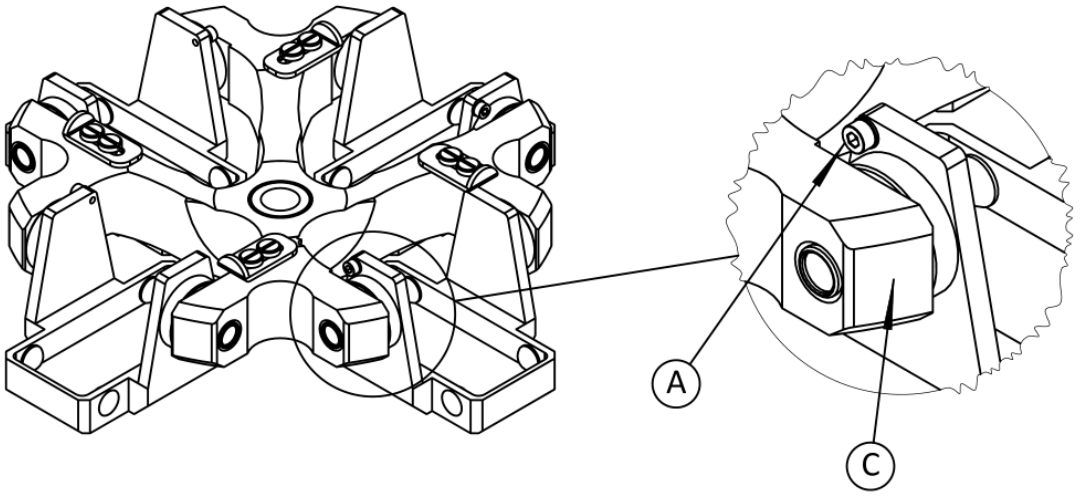

Figure 9 Placing hangers in the rotor

7.2. Centrifuging

- In order to improve the adhesion of cells to the microscope slide, it is recommended to cover them with phytolysin. Place the prepared and labeled microscope slide into the holder (with the manufacturer's marking facing up).
- Place a filter paper with a **Ø 9.5 mm** hole on the slide.
- Place the overlay in the support and evenly fasten its clasps.
- Pour the prepared fluid sample into the filling cylinder (max. 2 ml, marked with a line) and then plug the opening with a stopper.
- Close the sink cylinder with the plug.

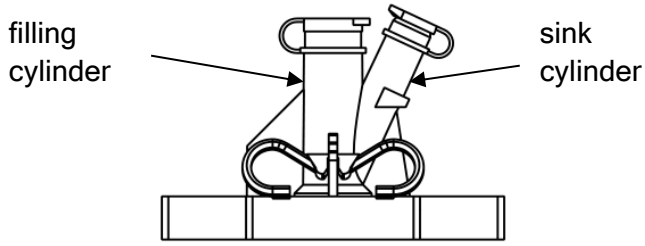

Figure 10 Cyto set prepared for centrifugation in the variant without obtaining supernatant

- Insert the CYTO sets (**4** or **2** in opposite sockets) into the hangers in the direction of the sink cylinders towards the rotor axis.

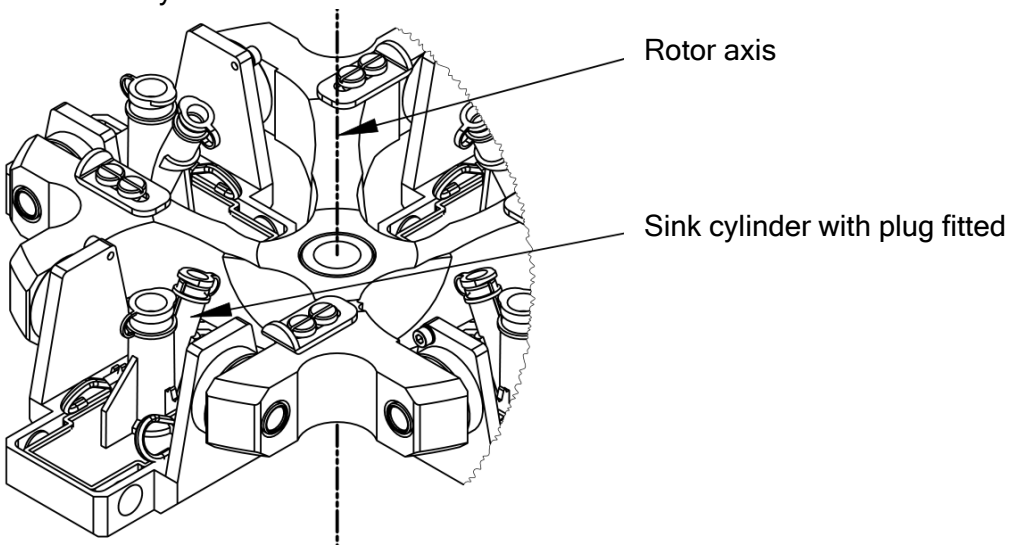

Figure 11 Method of placing CYTO sets in the rotor in the variant without obtaining supernatant

- Close the centrifuge lid.
- Set the spin speed and time.

Suggested spin parameters:

Spin speed	Time
1100 ÷ 1500 rpm	5 min

ATTENTION:
For **MPW-352, MPW-352R, MPW-352RH** centrifuges manufactured **up to 2018** (with serial numbers SN[2] up to 10352067918; 10352R050718; 10352RH009018) and **M-DIAGNOSTIC** produced **up to 2019** (serial no. SN up to 102MD011519) select the **acceleration characteristics with no. 3** (ACC) **and braking no. 6** (DEC)

[2] e.g., 10352067918, where 10352 stands for the symbol of the centrifuge, 0679 for the copy number, and 18 for the year of manufacture.

- Start spinning.
- After centrifuging, open the centrifuge lid.
- Take the set out of the rotor pendant keeping its **horizontal position**. Do not tilt the set, due to the possibility of spilling out the liquid from the base (supernatant) that has not been absorbed by the filter paper.
- Place the set on one-side foil paper and remove the clips from the catches. Then, in the place indicated by the arrow, gently press to lift the cap together with the microscope slide

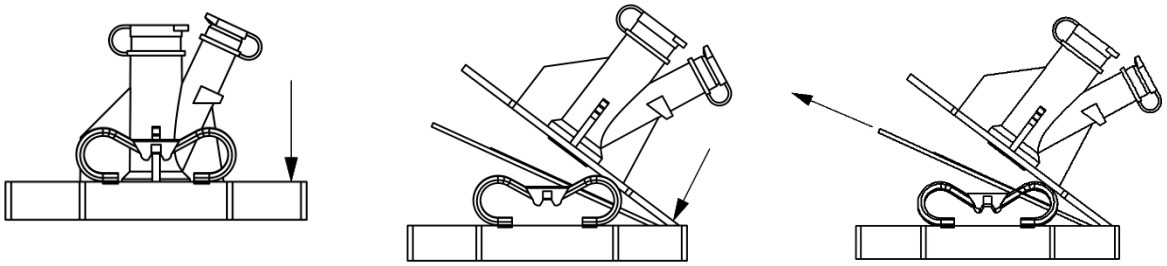

Figure 12 How to remove a microscope slide

- Carefully remove the slide, and then use the tweezers or tweezers to remove the filter paper. If necessary, repeat the centrifugation in order to dry the preparation, using a new filter paper **Ø 9.5 mm** and keeping the previously set centrifugation parameters. Fix the preparation formed on the slide and stain with selected techniques.

8. Disposal

The CYTO set 16610 is a single use product. After use, the set should be disposed of in accordance with the procedures in force in the laboratory.

9. Manufacturer

"MPW MED. INSTRUMENTS" SPÓŁDZIELNIA PRACY
Boremlowska 46 Street
04-347 Warsaw

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(+48) 22 879 70 46 (sales department - outside POLAND)
(+48) 22 610 81 07 (service)
fax: (+48) 22 610 55 36
e-mail: mpw@mpw.pl
website: www.mpw.pl

000042924 - number of entries in the Waste Database

PL/CA01-01782 - identification number given by Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.

10. Distributor's info

DISTRIBUTOR:

11. Declaration of conformity

no. DoC.16610.en_rev.1

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EU DECLARATION OF CONFORMITY

This EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Manufacturer:	"MPW MED. INSTRUMENTS" SPÓŁDZIELNIA PRACY 46 Boremlowska Street, 04-347 Warsaw, Poland
The Quality Management System complies with the standards:	PN-EN ISO 9001:2015, PN-EN ISO 13485:2016
SRN:	PL-MF-000032831
Product name:	CYTO set The set includes: 16611 CYTO base and insert, 16614 Microscope slide, 16616 Filter card with Ø 9,5 mm hole, 16617 Filter card with Ø 12,5 mm hole, 15123 Supernatant tube 2,2 ml.
Basic UDI-DI:	590538636-IVD-CEN-019-6S
Catalogue number:	16610

The aforementioned product is in conformity with the following EU regulation:

2017/746 (IVDR)	REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
Intended purpose:	CYTO set is an accessory for in vitro diagnostics medical devices, that is, the laboratory centrifuges specifically intended by the manufacturer for in vitro diagnostic (IVD) procedures. The set is used for the preparation and storage of the biological fluids intended for further in vitro diagnostics.
Risk class:	Class A (in accordance with the rule 5 of Annex VIII of Regulation (EU) 2017/746).

The conformity assessment of the product has been carried out in accordance with Article 48(10) of Regulation (EU) 2017/746.

Warsaw, 23 January 2023

Halina Ducka
Plenipotentiary of the Management Board

Łukasz Sałański
President of the Management Board

Suggestions regarding this manual should be directed to
https://mpw.pl/en/contact/contact-details

To find a local distributor, please visit
www.mpw.pl (CONTACT section, DISTRIBUTORS tab)

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