

УТВЕРЖДАЮ

Генеральный директор
ООО «Компания «БиВи»

Т.А. Носова

2022 г.



ПО ДОВЕРЕННОСТИ
77 АД 1754197
КУСАЙЛО Р.В.

Фотографические изображения изделия:

Анализатор 3-Diff автоматический гематологический для диагностики in vitro

Shenzhen Dymind Biotechnology Co., Ltd.,
(«Шэньчжэнь Дайминд Биотекнолоджи Ко., Лтд.»), Китай



Общий вид блока анализатора DH31 (Анализатор 3-Diff автоматический гематологический для диагностики in vitro, в варианте исполнения DH31)

Auto Hematology Analyzer

Model: DH31

Power: 100V-240V~ 50/60Hz 200VA

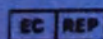


2022-12-04

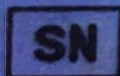


Shenzhen Dymind Biotechnology Co., Ltd.

10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community,
Yutang Street, Guangming District, Shenzhen 518107, P. R. China



Eunitor GmbH
Kennedydamm 5, 40476 Duesseldorf, Germany



DM10012249130



MADE IN CHINA

Общий вид шильдика на блоке анализатора (Анализатор 3-Diff автоматический гематологический для диагностики in vitro, в варианте исполнения DH31)



Общий вид блока анализатора DH33 (Анализатор 3-Diff автоматический гематологический для диагностики in vitro, в варианте исполнения DH33)

Auto Hematology Analyzer

Model: DH33

Power: 100V-240V~ 50/60Hz 200VA



2022-12-04



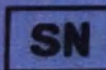
Shenzhen Dymind Biotechnology Co., Ltd.

10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community,
Yutang Street, Guangming District, Shenzhen 518107, P. R. China

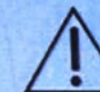


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Kennedydamm 5, 40476 Duesseldorf, Germany

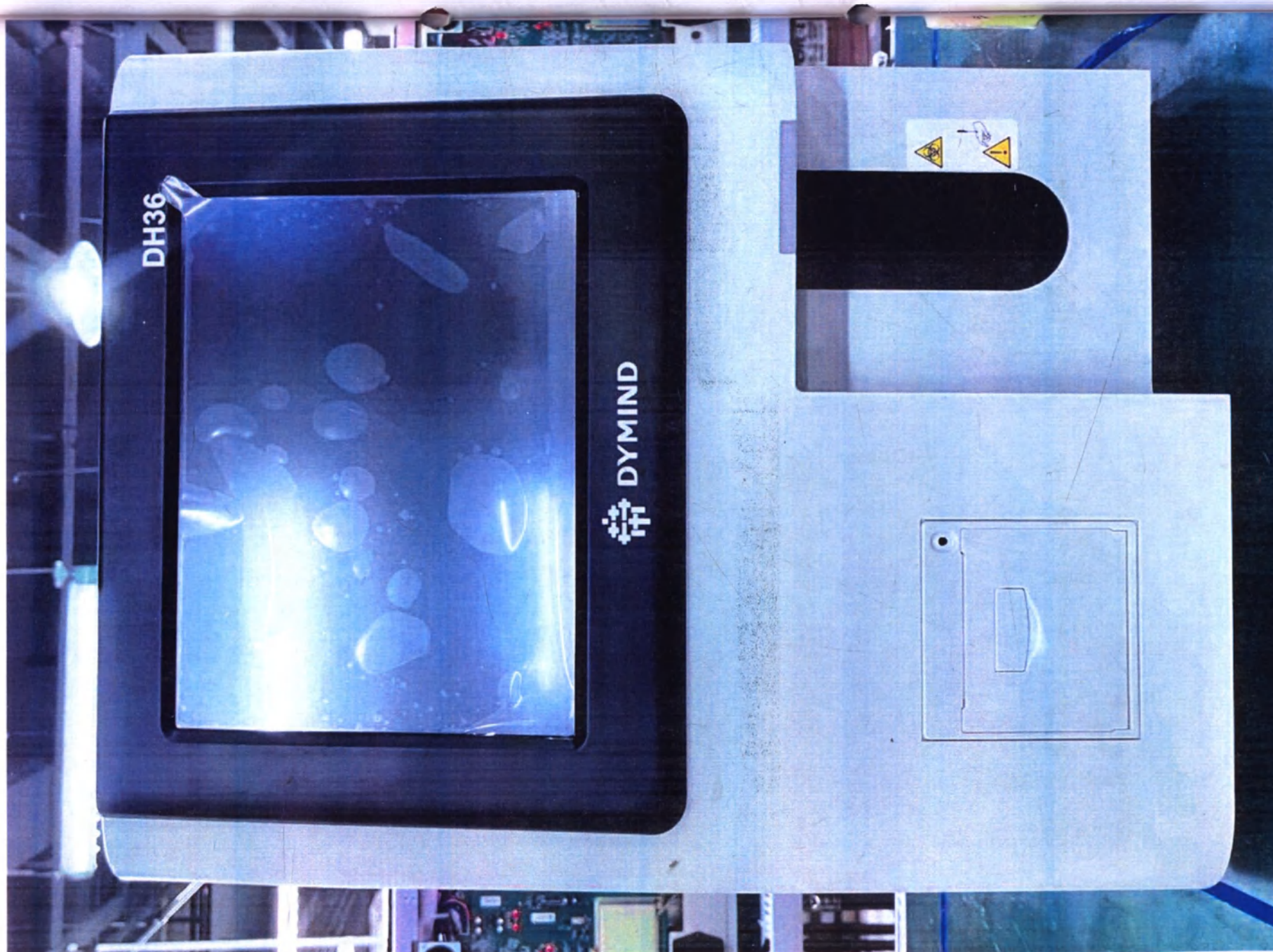


DM10012249129



MADE IN CHINA

Общий вид шильдика на блоке анализатора (Анализатор 3-Diff автоматический гематологический для диагностики in vitro, в варианте исполнения DH33)

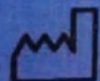


Общий вид блока анализатора DH36 (Анализатор 3-Diff автоматический гематологический для диагностики in vitro, в варианте исполнения DH36)

Auto Hematology Analyzer

Model: DH36

Power: 100V-240V~ 50/60Hz 200VA

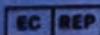


2022-12-04



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10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community,
Yutang Street, Guangming District, Shenzhen 518107, P. R. China



Eunitor GmbH

Kennedydamm 5, 40476 Duesseldorf, Germany



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MADE IN CHINA

Общий вид шильдика на блоке анализатора (Анализатор 3-Diff автоматический гематологический для диагностики in vitro, в варианте исполнения DH36)



Общий вид блока анализатора DH31X (Анализатор 3-Diff автоматический гематологический для диагностики in vitro, в варианте исполнения DH31X)

Auto Hematology Analyzer

Model: DH31X

Power: 100V-240V~ 50/60Hz 250VA



2022-10-02

IVD



Shenzhen Dymind Biotechnology Co., Ltd.

10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community,
Yutang Street, Guangming District, Shenzhen 518107, P. R. China

EC REP

Eunitor GmbH

Kennedydamm 5, 40476 Duesseldorf, Germany



CE

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DM10042241002

CLASS 1 LASER PRODUCT

IEC 60825-1:2014/
EN 60825-1:2014

Общий вид шильдика на блоке анализатора (Анализатор 3-Diff автоматический гематологический для диагностики in vitro, в варианте исполнения DH31X)



Общий вид блока анализатора DH33X (Анализатор 3-Diff автоматический гематологический для диагностики in vitro, в варианте исполнения DH33X)

Auto Hematology Analyzer

Model: DH33X

Power: 100V-240V~ 50/60Hz 250VA



2022-10-02

IVD



Shenzhen Dymind Biotechnology Co., Ltd.

10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community,
Yutang Street, Guangming District, Shenzhen 518107, P. R. China

EC REP

Eunitor GmbH

Kennedydamm 5, 40476 Duesseldorf, Germany

SN



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Общий вид шильдика на блоке анализатора (Анализатор 3-Diff автоматический гематологический для диагностики in vitro, в варианте исполнения DH33X)



Общий вид блока анализатора DH36X (Анализатор 3-Diff автоматический гематологический для диагностики in vitro, в варианте исполнения DH36X)

Auto Hematology Analyzer

Model: DH36X

Power: 100V-240V~ 50/60Hz 250VA



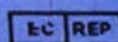
2022-06-11

IVD



Shenzhen Dymind Biotechnology Co., Ltd.

10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community,
Yutang Street, Guangming District, Shenzhen 518107, P. R. China



Eunitor GmbH

Kennedydamm 5, 40476 Duesseldorf, Germany



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DM10042224002

CLASS 1 LASER PRODUCT

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Общий вид шильдика на блоке анализатора (Анализатор 3-Diff автоматический гематологический для диагностики in vitro, в варианте исполнения DH36X)



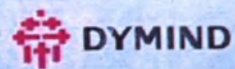
Кабель питания, 37.01.0046A, Dongguan Risheng Electric Wire Co., Ltd.

(Анализатор 3-Diff автоматический гематологический для диагностики in vitro, в вариантах исполнения DH31, DH33, DH36, DH31X, DH33X, DH36X)



Кабель периферийного заземления, 37.03.0001A, Shenzhen Kepute Electronics Co., Ltd.

(Анализатор 3-Diff автоматический гематологический для диагностики in vitro, в вариантах исполнения DH31, DH33, DH36, DH31X, DH33X, DH36X)



Auto Hematology Analyzer
Operator's Manual

400 988 7229
www.dymind.com

Руководство по эксплуатации

(Анализатор 3-Diff автоматический гематологический для диагностики in vitro, в вариантах исполнения DH31, DH33, DH36, DH31X, DH33X, DH36X)

Startup

1. Place the power switch on the back of the analyzer in the [I] position to start the analyzer.
2. Enter the username and password on the screen.
3. The startup initialization and cleaning procedures begin. After the procedures, you can perform operations on the user interface.

Daily Quality Control

Before running samples every day, run the controls in the QC interface. For details, see the section about quality control in *Operator's Manual*.



Running the Whole Blood Samples

1. Click Mode & ID in the Sample Analysis screen.
2. Select Venous Whole Blood (VWB) or Capillary Whole Blood (CWB) as required.
3. Input the sample ID for the sample to be run, then click OK.
4. Set the well-mixed sample (uncapped) below the sample probe, press the aspirate key to start the analysis. Remove the tube when you hear a beep.

NOTE: The tube should be placed vertically upward, not tilted or upside down.

Running the Predilute Samples

1. Click Mode & ID in the Sample Analysis screen.
2. Select Predilute, input the sample ID for the sample to be run, then click OK.

3. Click Add Diluent on the menu screen, present a clean centrifugal tube (uncapped) under the sample probe.



4. Press the aspirate key. When you hear a beep, remove the tube. If more portions of diluent are needed, take another clean centrifugal tube and repeat this step.
5. Click Cancel to exit the diluent dispensing.
6. Add 20µL of capillary blood to the diluent, close the tube cap and shake the tube to mix the sample.

NOTE: The centrifugal tube should be placed vertically upward, not tilted or upside down.

7. Uncap the centrifugal tube and present it to the sample probe so that the probe tip is vertically in contact with the bottom of the tube, then press the aspirate key to start the analysis. Remove the tube when you hear a beep.

Shutdown

NOTE

Shut down strictly as instructed on screen, and on the shutdown maintenance with the cleanser.

1. Click  on the menu screen, perform the shutdown procedure by following the screen instructions.
2. Turn off the power switch of the analyzer.



3. Empty the waste container and dispose of the waste properly.

Precautions

Troubleshooting

If an error occurs, the error message displays at the top of the screen. To remove the error, click the error message area, and click Remove Error. For details, see the Troubleshooting chapter in *Operator's Manual*.

When the analyzer prompts that the diluent is running out or waste is full (actually the diluent is enough and the waste is not full), please take out the corresponding sensor from the container to shake 2~3 times, then put it back. Click Remove Error to remove the error. If the error still exists, contact our customer service department.

Replacing Reagents

Once the new reagent is connected, see the section about reagent management in *Operator's Manual* for reagents replacement.

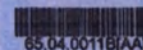
Routine Maintenance

Maintenance Scenarios	Operations
Shutdown or daily tips	Perform cleanser maintenance as instructed.
Before a short distance transport (transporting time ≤ 2h)	Perform Empty Fluidics.
Not to be used for over one week or a long distance transport (transporting time > 2h)	Perform Prepare to Ship.

Sleep

The analyzer enters sleep mode when no operation is done for a specified interval. You can touch the screen to wake up the analyzer.

For detailed instructions and precautions of the analyzer, see the *Operator's Manual*.



Startup

1. Place the power switch on the back and the left side of the analyzer in the (I) position to start the analyzer.
2. Enter the username and password on the interface.
3. The startup initialization and cleaning procedures begin. After the procedures, you can perform operations on the user interface.

Daily Quality Control

Before running samples every day, run the controls in the QC interface. For details, see the section about quality control in *Operator's Manual*.



Running the Venous Whole Blood and Capillary Whole Blood Samples

1. Click **Mode & ID** in the Sample Analysis screen.
2. Select **Venous Whole Blood (VWB)** or **Capillary Whole Blood (CWB)** as required.
3. Select the measurement mode as required and input the sample ID for the sample to be run, then click **OK**.
4. Set the well-mixed sample (uncapped) below the sample probe, press the aspirate key to run the sample. Remove the tube when you hear a beep.

NOTE: The tube shall be placed vertically upward, not tilted or upside down.

Running the Predilute Samples

1. Click **Mode & ID** in the Sample Analysis interface to set the analysis mode and select **Predilute**.
2. Select the measurement mode as required and input the sample ID for the sample to be run, then click **OK**.

3. Click **Add Diluent** on the menu interface, then present a clean centrifugal tube under the sample probe.



4. Press the aspirate key. When you hear a beep, remove the tube. If more portions of diluent are needed, take another clean centrifugal tube and repeat this step.
5. Click **Cancel** to exit the diluent dispensing.
6. Add 20µL of blood to the diluent, close the tube cap and shake the tube to mix the sample.

NOTE: The centrifugal tube shall be placed vertically upward, not tilted or upside down.

7. Uncap the centrifugal tube and present it to the sample probe so that the probe tip is vertically in contact with the bottom of the tube, then press the aspirate key to run the sample. Remove the tube when you hear a beep.

Shutdown

NOTE

To keep special protein reagent in cold temperature, do not turn off the power switch on the back of the main unit (except special occasions like transportation or long-term non-use of CRP measurement).

Shut down strictly as instructed on-screen, and do the shutdown maintenance with the cleanser.

1. Click  on the menu interface, perform the shutdown procedure by following the screen instructions.



2. Turn off the power switch at the left side of the analyzer.
3. Empty the waste container and dispose of the waste properly.

Precautions

Troubleshooting

If an error occurs, the error message displays on the top of the interface. To remove the error, double click the message area, and click Remove Error.

When the analyzer prompts that the diluent is running out or waste is full error (actually the diluent is enough and the waste is not full), please take out the corresponding sensor from the container to shake 2-3 times, then put it back. Click Remove Error to remove the error.

Replacing Reagents

Once the new reagent is connected, see the section about reagent management in *Operator's Manual* for reagents replacement.

Routine Maintenance

Maintenance Scenarios	Operations
Shutdown or daily tips	Perform cleanser maintenance procedure as instructed.
Not to be used for 1-2 weeks or before a short distance transport (transporting time ≤ 2h)	Perform Empty Fluidics.
Not to be used for more than 2 weeks or a long distance transport (transporting time > 2h)	Perform Prepare to Ship.

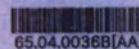
NOTE

For dry areas, the operation of **Empty Fluidics** should be carried out when the analyzer has not been used for two to three days, and the operation of **Prepare to Ship** should be carried out when the analyzer has not been used for more than three days.

Sleep

The analyzer enters sleep mode when no operation is done for a specified interval. You can touch the screen to wake up the analyzer.

For detailed instructions and precautions of the analyzer, see the *Operator's Manual*.





Трубка для разбавителя, 20.01.0037A, Shenzhen Dymind Biotechnology Co., Ltd.



Трубка для отходов, 20.01.0038А, Shenzhen Dymind Biotechnology Co., Ltd.



Трубка для отходов, 20.01.0981A, Shenzhen Dymind Biotechnology Co., Ltd.



Контейнер для отходов, 66.99.0002A, ChangZhou ChangShun Medical Technology Co., Ltd



Сканер штрих-кода, 50.99.0041A, Shenzhen Venture IOT Technology Co., Ltd.



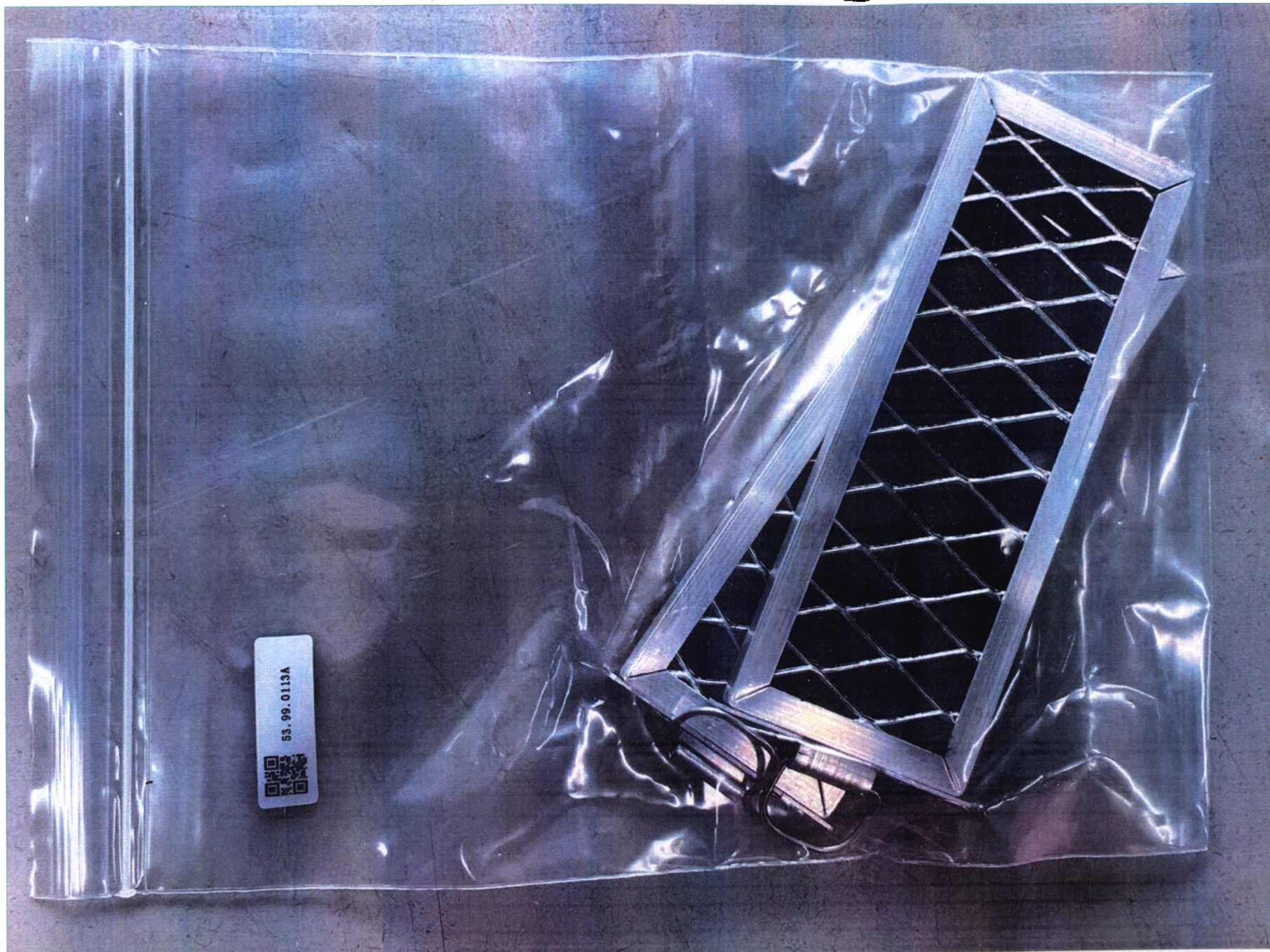
Кабель передачи данных, 37.02.0030A, Shenzhen Zhitongcheng Electronic Co., Ltd.



Трубка для лизирующего реагента LYE-1, 20.01.0036A, Shenzhen Dymind Biotechnology Co., Ltd.



Фильтр воздушный, 53.99.0018A, Shenzhen Hongchuangjia Electronics Co., Ltd.
(Анализатор 3-Diff автоматический гематологический для диагностики in vitro, в вариантах исполнения DH31X, DH33X, DH36X)



Фильтр приточного воздуха CRP, 53.99.0113A, Shenzhen Yijin Technology Co., Ltd.

Всего прошито, пронумеровано и скреплено
печатью и подписью: 29 листа (-ов)

Генеральный директор _____ / Носова Т.А
М.П.



ПО ДОВЕРЕННОСТИ
77 АД 1754187
КУСАКОВ В.В.

