

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Anexa nr. 2
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: _____ TRIUMF MOTIV SRL _____, cu
sediul _____ or. Chișinău str. Grenoble 193 _____,

declar pe proprie răspundere, cunoscând prevederile art. **352¹**, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

Denumire generică (denumirea dispozitivului)	Modelul
TopPette Mechanical Pipette	7010101004

Sunt autentice și corespund realității.

Numele, prenumele și funcția Jighili Tatiana, Administrator
Semnătura _____

Data 27.07.2023

BIOBASE

Biobase Biodustry(Shandong) Co., Ltd.

Mingshui Economic Development Zone, Zhangqiu District, Jinan City, Shandong, China (Biobase Industrial Park in a intersection of East Jingshi Road and Mingbu Road)

TEL: +86-531-66777727 FAX: +86-531-81219804

E-MAIL: sales_middleeast@biobase.com WEBSITE: www.biobase.cc

AUTHORIZATION LETTER

Date: June 9, 2023

To whom it can refer

We, Biobase Biodustry(Shandong) Co., Ltd.

Address: Mingshui Economic Development Zone, Zhangqiu District, Jinan City, Shandong, China (Biobase Industrial Park in a intersection of East Jingshi Road and Mingbu Road)

hereby authorizes your company:

Triumf Motiv SRL

Republic Of Moldova, MD 2043-str. Grenoble 193, et.13, of.1

tel: (+373 22) 76 84 62, 76 88 41

Triumf-Motiv SRL is our authorized representative and distributor on the territory of the Republic of Moldova.

We allow this company to register our products with the competent authorities on the territory of the Republic of Moldova, as well as to promote, sell, distribute our products in the Republic of Moldova, and we will provide all necessary assistance to expand the market of medical supplies and devices of our brand in your country.

This letter of authorization remains valid for five years, starting from June 9, 2023 and expiring on June 9, 2028.

Name: Erica Zhang

Title: Sales Manager

Signature:



BIOBASE

Biobase Biodustry(Shandong) Co., Ltd.

ADD: Mingshui Economic Development Zone, Zhangqiu District, Jinan City, Shandong, China
(Biobase Industrial Park in a intersection of East Jingshi Road and Mingbu Road) TEL: +86-531-81219803 FAX: +86-531-81219804
E-MAIL: export@biobase.cn WEBSITE: www.biobase.cc / www.meihuatrade.com

DECLARATION OF CONFORMITY

Technical file of the company mentioned below has been inspected and audit has been completed successfully

2006/42/EC Machinery Directive have been taken as reference for these processes

Company Name: **Biobase Biodustry(Shandong) Co., Ltd.**
Mingshui Economic Development Zone, Zhangqiu District, Jinan City, Shandong, China (Biobase Industrial Park in a intersection of East Jingshi Road and Mingbu Road)

Brand: **BIOBASE**

Related Directives and Annex: 2006/42/EC Machinery Directive (MD)

Related Standards: **EN ISO 12100:2010**

Product(s): **Pipette Stand**

Type(s)/Model(s): 7030000084, 7030000085

Classification: **Laboratory Equipment**

Examination Period: March 04, 2022

Date of Expiry: March 03, 2027

Review Result: We, Biobase Biodustry(Shandong) Co., Ltd., declare that during the self-testing and performance evaluation, no Non-compliance according to the requirements of the 2006/42/EC Machinery Directive was detected.

Year of DOC marking: **2022**

Signed for and on behalf of

Company: **Biobase Biodustry(Shandong) Co., Ltd.**

RA Specialist:

Chloe Chang

Document No: **BKSD-CC22030405**



Version: BKSD2021 MD DOC 1.0

BIOBASE

Biobase Biodustry(Shandong) Co., Ltd.

ADD: Mingshui Economic Development Zone, Zhangqiu District, Jinan City, Shandong, China
(Biobase Industrial Park in a intersection of East Jingshi Road and Mingbu Road) TEL: +86-531-81219803 FAX: +86-531-81219804
E-MAIL: export@biobase.cn WEBSITE: www.biobase.cc / www.meihuatrade.com

DECLARATION OF CONFORMITY

Technical file of the company mentioned below has been inspected and audit has been completed successfully

2006/42/EC Machinery Directive have been taken as reference for these processes

Company Name: **Biobase Biodustry(Shandong) Co., Ltd.**
Mingshui Economic Development Zone, Zhangqiu District, Jinan City, Shandong, China (Biobase Industrial Park in a intersection of East Jingshi Road and Mingbu Road)

Brand: **BIOBASE**

Related Directives and Annex: 2006/42/EC Machinery Directive (MD)

Related Standards: **EN ISO 12100:2010**

Product(s): **TopPette Mechanical Pipette**

Type(s)/Model(s): 0.1-2.5µL, 0.5-10µL, 2-20µL, 10-100µL, 50-200µL, 200-1000µL

Classification: **Laboratory Equipment**

Examination Period: March 04, 2022

Date of Expiry: March 03, 2027

Review Result: We, Biobase Biodustry(Shandong) Co., Ltd., declare that during the self-testing and performance evaluation, no Non-compliance according to the requirements of the 2006/42/EC Machinery Directive was detected.

Year of DOC marking: **2022**

Signed for and on behalf of

Company: **Biobase Biodustry(Shandong) Co., Ltd.**

RA Specialist:

Chloe cheng

Document No: **BKSD-CC22030402**



Version: BKSD2021 MD DOC 1.0

BIOBASE

Biobase Biodustry(Shandong) Co., Ltd.

ADD: Biobase Industrial Park in a intersection of East JingshiRoad and Mingbu Road

TEL: +86-531-81219803 FAX: +86-531-81219804

E-MAIL: export@biobase.cn WEBSITE: www.biobase.cc / www.meihuatrade.com

DECLARATION OF CONFORMITY

Technical file of the company mentioned below has been inspected and audit has been completed successfully

2006/42/EC Machinery Directive have been taken as reference for these processes

Company Name: **Biobase Biodustry(Shandong) Co., Ltd.**
Mingshui Economic Development Zone, Zhangqiu District,
JinanCity, Shandong, China (Biobase Industrial Park in a
intersection of East JingshiRoad and Mingbu Road)

Brand: **BIOBASE**

Related Directives and Annex: Machinery Directive 2006/42/EC

Related Standards: **EN ISO 12100:2010**

Product(s): **MicroPette Mechanical Pipette (Eight Channels)**

Type(s)/Model(s): **7030203004**

Classification: **Laboratory Equipment**

Examination Period: **Maech 01, 2022**

Date of Expiry: **February 28, 2027**

Review Result: We, Biobase Biodustry(Shandong) Co., Ltd., declare that
during the self-testing and performance evaluation, no
Non-compliance according to the requirements of the
2006/42/EC Machinery Directive was detected.

Year of DOC marking: **2022**

Signed for and on behalf of

Company: **Biobase Biodustry(Shandong) Co., Ltd.**

RA Specialist: *Chloe Chen*

Document No: **MD-CC22030103**



质量管理体系 认证证书

证书号：HXC18921Q20254R0M

兹 证 明

山东博科生物产业有限公司

统一社会信用代码：9137018179889855X7

注册地址：山东省济南市章丘区明水经济开发区（经十东路与明埠路交界山东博科产业园）

办公地址：山东省济南市章丘区明水经济开发区（经十东路与明埠路交界山东博科产业园）

生产/经营地址：山东省济南市工业南路 51 号（生产）/济南市章丘明水经济开发区经十东路与明埠路交界
山东博科产业园（研发、生产、销售）/济南市章丘明水经济开发区清河大街 2 号鑫岳工业园 8#（生产）
/山东省济南市平阴县锦水高端装备制造产业园 3 号标准厂房（生产）

邮编：250200

质量管理体系符合

GB/T 19001-2016 / ISO 9001:2015 标准条款的要求

该体系认证所覆盖的范围

用于体外诊断试剂盒、生物安全柜、医用气溶胶吸附器、血液冷藏箱、医用恒温箱、
全自动酶免工作站、血细胞分析用稀释液、血细胞分析用溶血剂、洗板机、医用冷藏箱、
全自动生化分析仪、全自动化学发光测定仪、核酸提取仪、全自动核酸提取仪、
一次性使用病毒采样管、医用离心机的研发、生产和销售（资质许可范围内）

第一次监审	贴标处	第二次监审	贴标处	第三次监审	贴标处
-------	-----	-------	-----	-------	-----

证书有效期内，获证组织须每年至少接受一次监督审核并加贴合格标志，证书方为有效。
本证书信息可在国家认证认可监督管理委员会官方网站：www.cnca.gov.cn查询。
证书有效性以右侧二维码扫描内容为准



张建设



初次获证日期：2021 年 7 月 5 日

签发日期：2021 年 7 月 5 日

有效日期：2024 年 7 月 4 日

北京市昌平区城北街道鼓楼南街 6 号 2 号楼 802 室

www.hxccc.org

010-57146599

No. 0002277

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certification No. : HXC18921Q20254R0M

Awarded to

Biobase Biodustry(Shandong)Co., Ltd.

Organization Code: 9137018179889855X7

Registration Add.: Mingshui Economic Development Zone,Zhangqiu District,Jinan City, Shandong Province
(Biobase Industrial Park in a intersection of East Jingshi Road and Mingbu Road)

Office Add.: Mingshui Economic Development Zone,Zhangqiu District,Jinan City, Shandong Province
(Biobase Industrial Park in a intersection of East Jingshi Road and Mingbu Road)

Production/Service Add.: No.51 Industrial South road,Jinan City, Mingshui Economic Development Zone,
Zhangqiu District,Jinan City(Biobase Industrial Park in a intersection of East Jingshi Road and Mingbu Road),
No.2 Qinghe street, Zhangqiu District, Jinan City,Standard Plant No. 3, Jinshui High-end Equipment
Manufacturing Industrial Park, Pingyin County, Jinan City, Shandong Province

Zip Code: 250200

**The Quality Management System of the above
organization has been assessed and Found to be in accordance with
the requirements of the standard:**

GB/T 19001-2016 / ISO 9001:2015

Scope of this management Certification

**R&D, production and sales of In Vitro Diagnostic Reagents, Biological Safety Cabinets,
Air Purifier, Blood Bank Refrigerator, Medical Incubator, Automatic ELISA Processor,
Hematology Analyzer Diluent, Hematology Analyzer Lyse, Microplate Washer,
Laboratory Refrigerator, Automatic chemistry analyzer, Automatic Chemiluminescence Analyzer,
Automatic Nucleic acid extration system, Disposable Virus Sampling Tube,
Medical centrifuge (within the scope of qualification license)**

First S.A.	Labelling	Second S.A.	Labelling	Third S.A.	Labelling
------------	-----------	-------------	-----------	------------	-----------

The certified organization must accept at least one surveillance audit annually and a qualified mark shall be attached onto the certificate, within validity period of the certificate, then the certificate can be maintained valid.

For more details of this certificate, please login CNCA' s website: www.cnca.gov.cn.

For the validity of the certificate, please scan the QR codes on the right ride for accurate information.



张建设



Date of Issue:5 Jul. 2021 Date of Supervision:5 Jul. 2021 Valid until:4 Jul. 2024

Room 802, 2nd Building, No. 6 South Street of Gulou, Changping District, Beijing City, China 010-57146599

No. 0002277

质量管理体系 认证证书

证书号：HXC18921Q20254R0M

兹 证 明

山东博科生物产业有限公司

统一社会信用代码：9137018179889855X7

注册地址：山东省济南市章丘区明水经济开发区（经十东路与明埠路交界山东博科产业园）

办公地址：山东省济南市章丘区明水经济开发区（经十东路与明埠路交界山东博科产业园）

生产/经营地址：山东省济南市工业南路 51 号（生产）/济南市章丘明水经济开发区经十东路与明埠路交界山东博科产业园（研发、生产、销售）/济南市章丘明水经济开发区清河大街 2 号鑫岳工业园 8#（生产）
/山东省济南市平阴县锦水高端装备制造产业园 3 号标准厂房（生产）

邮编：250200

质量管理体系符合

GB/T 19001-2016 / ISO 9001:2015 标准条款的要求

该体系认证所覆盖的范围

用于体外诊断试剂盒、生物安全柜、医用气溶胶吸附器、血液冷藏箱、医用恒温箱、全自动酶免工作站、血细胞分析用稀释液、血细胞分析用溶血剂、洗板机、医用冷藏箱、全自动生化分析仪、全自动化学发光测定仪、核酸提取仪、全自动核酸提取仪、一次性使用病毒采样管、医用离心机的研发、生产和销售（资质许可范围内）

第一次监审	贴标处	第二次监审	贴标处	第三次监审	贴标处
-------	-----	-------	-----	-------	-----

证书有效期内，获证组织须每年至少接受一次监督审核并加贴合格标志，证书方为有效。
本证书信息可在国家认证认可监督管理委员会官方网站：www.cnca.gov.cn查询。
证书有效性以右侧二维码扫描内容为准



张建设



初次获证日期：2021 年 7 月 5 日

签发日期：2021 年 7 月 5 日

有效日期：2024 年 7 月 4 日

北京市昌平区城北街道鼓楼南街 6 号 2 号楼 802 室

www.hxccc.org

010-57146599

No.0002277

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certification No. : HXC18921Q20254R0M

Awarded to

Biobase Biodustry(Shandong)Co., Ltd.

Organization Code: 9137018179889855X7

Registration Add.: Mingshui Economic Development Zone,Zhangqiu District,Jinan City, Shandong Province
(Biobase Industrial Park in a intersection of East Jingshi Road and Mingbu Road)

Office Add.: Mingshui Economic Development Zone,Zhangqiu District,Jinan City, Shandong Province
(Biobase Industrial Park in a intersection of East Jingshi Road and Mingbu Road)

Production/Service Add.: No.51 Industrial South road,Jinan City, Mingshui Economic Development Zone,
Zhangqiu District,Jinan City(Biobase Industrial Park in a intersection of East Jingshi Road and Mingbu Road),

No.2 Qinghe street, Zhangqiu District, Jinan City,Standard Plant No. 3, Jinshui High-end Equipment

Manufacturing Industrial Park, Pingyin County, Jinan City, Shandong Province

Zip Code: 250200

**The Quality Management System of the above
organization has been assessed and Found to be in accordance with
the requirements of the standard:**

GB/T 19001-2016 / ISO 9001:2015

Scope of this management Certification

**R&D, production and sales of In Vitro Diagnostic Reagents, Biological Safety Cabinets,
Air Purifier, Blood Bank Refrigerator, Medical Incubator, Automatic ELISA Processor,
Hematology Analyzer Diluent, Hematology Analyzer Lyse, Microplate Washer,
Laboratory Refrigerator, Automatic chemistry analyzer, Automatic Chemiluminescence Analyzer,
Automatic Nucleic acid extration system, Disposable Virus Sampling Tube,
Medical centrifuge (within the scope of qualification license)**

First S.A.	Labelling	Second S.A.	Labelling	Third S.A.	Labelling
------------	-----------	-------------	-----------	------------	-----------

The certified organization must accept at least one surveillance audit annually and a qualified mark shall be attached onto the certificate, within validity period of the certificate, then the certificate can be maintained valid.

For more details of this certificate, please login CNCA' s website: www.cnca.gov.cn.

For the validity of the certificate, please scan the QR codes on the right ride for accurate information.



张建设



Date of Issue:5 Jul. 2021 Date of Supervision:5 Jul. 2021 Valid until:4 Jul. 2024

Room 802, 2nd Building, No. 6 South Street of Gulou, Changping District, Beijing City, China 010-57146599

No. 0002277

医疗器械质量管理体系 认证证书

证书号：HXC18921YL008R0M

兹 证 明

山东博科生物产业有限公司

统一社会信用代码：9137018179889855X7

注册地址：山东省济南市章丘区明水经济开发区（经十东路与明埠路交界山东博科产业园）

办公地址：山东省济南市章丘区明水经济开发区（经十东路与明埠路交界山东博科产业园）

生产/经营地址：山东省济南市工业南路 51 号（生产）/济南市章丘明水经济开发区经十东路与明埠路交界
山东博科产业园（研发、生产、销售）/济南市章丘明水经济开发区清河大街 2 号鑫岳工业园 8#（生产）
/山东省济南市平阴县锦水高端装备制造产业园 3 号标准厂房（生产）

邮编：250200

医疗器械质量管理体系符合

ISO 13485: 2016 标准要求

通过认证的范围为

用于体外诊断试剂盒、生物安全柜、医用气溶胶吸附器、血液冷藏箱、医用恒温箱、
全自动酶免工作站、血细胞分析用稀释液、血细胞分析用溶血剂、洗板机、医用冷藏箱、
全自动生化分析仪、全自动化学发光测定仪、核酸提取仪、全自动核酸提取仪、
一次性使用病毒采样管、医用离心机的研发、生产和销售（资质许可范围内）

第一次监审	贴标处	第二次监审	贴标处	第三次监审	贴标处
-------	-----	-------	-----	-------	-----

证书有效期内，获证组织须每年至少接受一次监督审核并加贴合格标志，证书方为有效。
本证书信息可在国家认证认可监督管理委员会官方网站：www.cnca.gov.cn查询。
证书有效性以右侧二维码扫描内容为准



张建设



初次获证日期：2021 年 7 月 5 日

签发日期：2021 年 7 月 5 日

有效日期：2024 年 7 月 4 日

北京市昌平区城北街道鼓楼南街 6 号 2 号楼 802 室

010-57146599

MEDICAL DEVICES QUALITY MANAGEMENT SYSTEMS CERTIFICATE

Certification No. : HXC18921YL008R0M

Awarded to
Biobase Biodustry(Shandong)Co., Ltd.

Organization Code: 9137018179889855X7

Registration Add.: Mingshui Economic Development Zone,Zhangqiu District,Jinan City, Shandong Province
(Biobase Industrial Park in a intersection of East Jingshi Road and Mingbu Road)

Office Add.: Mingshui Economic Development Zone,Zhangqiu District,Jinan City, Shandong Province
(Biobase Industrial Park in a intersection of East Jingshi Road and Mingbu Road)

Production/Service Add.: No.51 Industrial South road,Jinan City, Mingshui Economic Development Zone,
Zhangqiu District,Jinan City(Biobase Industrial Park in a intersection of East Jingshi Road and Mingbu Road),
No.2 Qinghe street, Zhangqiu District, Jinan City,Standard Plant No. 3, Jinshui High-end Equipment
Manufacturing Industrial Park, Pingyin County, Jinan City, Shandong Province

Zip Code: 250200

**The Medical Devices Quality Management Systems of the above
Organization has been assessed and Found to be in accordance with
the requirements of the standard:**

ISO 13485:2016

Scope of this management Certification

**R & D, production and sales of In Vitro Diagnostic Reagents, Biological Safety Cabinets,
Air Purifier, Blood Bank Refrigerator, Medical Incubator, Automatic ELISA Processor,
Hematology Analyzer Diluent, Hematology Analyzer Lyse, Microplate Washer,
Laboratory Refrigerator, Automatic chemistry analyzer, Automatic Chemiluminescence Analyzer,
Automatic Nucleic acid extration system, Disposable Virus Sampling Tube,
Medical centrifuge (within the scope of qualification license)**

First S.A.	Labelling	Second S.A.	Labelling	Third S.A.	Labelling
------------	-----------	-------------	-----------	------------	-----------

The certified organization must accept at least one surveillance audit annually and a qualified mark shall be attached onto the certificate, within validity period of the certificate, then the certificate can be maintained valid.

For more details of this certificate, please login CNCA' s website: www.cnca.gov.cn.

For the validity of the certificate, please scan the QR codes on the right ride for accurate information.



张建设



Date of Issue:5 Jul. 2021 Date of Supervision:5 Jul. 2021 Valid until:4 Jul. 2024

Room 802,2nd Building,No.6 South Street of Gulou,Changping District,Beijing City,China 010-57146599