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





ZEVENS.



有效日期: 2024 年 7 月 4 日 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.









质量管理体系 认证证书

证书号: HXC18921Q20254ROM

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

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初次获证日期: 2021年7月5日

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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

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certification No.: HXC18921Q20254R0M

Awarded to

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Ultrasonic Cleaner Single Frequency Type

Introduction:

Ultrasonic cleaning is a process that uses ultrasonic and an appropriate cleaning solvent to clean items.

Features:

- * Standard basket and lid.
- * Time and temperature real-time display.
- * Fully microprocessor controller and programmable.
- * Digital display, easy operation for time and temperature.
- * Low-level water protection (UC-20S, UC-20SII, UC-30S, UC-30SII, UC-50S, UC-60S, UC-70S).
- * Standard Power Supply: AC220v±10%, 50/60Hz; 110V±10%, 60Hz (Except for UC-5S, UC-10S, UC-20S, UC-20SII).

40KHz

Technical Parameters:

Model	Capacity	Ultrasonic	Time Range	Ultrasonic	Heating	Tank Size	Packing Size	Gross
	(L)	Frequency	/Heating Temp	Power(W)	Power(W)	L*W*H(mm)	L*W*H(mm)	Weight(kg)
UC-08A	1.3		1~30min /20~80°C	60	200	150*140*65	260*260*260	2.5
UC-10A	2			60	200	150*140*100	260*260*290	3
UC-20A	3	40KHz		120	200	240*135*100	350*260*330	4
UC-30A	6			180	400	300*150*150	430*280*380	6
UC-40A	10			240	400	300*240*150	430*370*380	8
UC-50A	14			300	400	300*240*200	430*370*430	9
UC-60A	15			360	600	330*300*150	460*430*390	10
UC-70A	19			420	600	330*300*200	460*430*430	11
UC-80A	22			480	800	500*300*150	630*430*390	13
UC-100A	30			600	1000	500*300*200	630*430*430	15
UC-5S	2		1~480min /RT~80°C	50	100	150*140*100	260*260*280	3.5
UC-10S	4			100	400	300*150*100	445*250*400	8.5
UC-20S	6	80KHz		200	400	300*150*150	435*240*430	8.8
UC-20SII	8			200	400	300*150*180	505*355*495	13
UC-30S	10			300	400	300*240*150	446*346*463	12.1
UC-30SII	13		1~480min /0~80°C	300	400	300*240*180	840*670*730	75
UC-50S	27			500	800	500*300*180	1100*690*820	99
UC-60S	27			600	800	500*300*180	1100*690*820	101
UC-70S	27			700	800	500*300*180	1100*690*820	101

Double Adjustable Frequencies Type

Features:

- * Over-voltage and over-current protection.
- * Standard basket and lid.
- * Low-level water protection.
- * Fully microprocessor controlled and programmable.
- * Digital display, easy setting for time and temperature.
- * Time and temperature real-time display.
- * Standard Power Supply: AC220v±10%, 50/60Hz;110V±10%, 60Hz (Except for UC-10SD, UC-10SDII, UC-20SD, UC-20SDII, UC-30SD).

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Technical Parameters:

Model	Capacity (L)	Ultra	stable sonic uency	Time Range	Ultrasonic Power(W)	Heating Power(W)	Tank Size L*W*H(mm)	Packing Size L*W*H(mm)	Gross Weight(kg)
UC-30SDG	13	45	80		300	400	300*240*180	840*670*730	73
UC-50SD	27	45	80	1~480min	500	800	500*300*180	1100*690*800	101
UC-60ST	27	45	80	/0~80°C	600	800	500*300*180	1100*690*800	102
UC-70ST	27	45	80		700	800	500*300*180	1100*690*800	104
UC-10SD	3	45	80		100	400	230*140*100	446*250*400	7
UC-10SDII	4	45	80		100	400	230*140*130	446*346*453	12
UC-20SD	6	45	80	1~480min	200	400	300*150*150	445*250*430	9.5
UC-20SDII	8	45	80	/RT~80°C	200	400	300*150*180	500*350*480	15.5
UC-30SD	10	45	80		300	400	300*240*150	446*346*483	12.5
UC-30SDII	13	45	80		300	400	300*240*180	650*540*630	37

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BIOBASE®

DIGITAL ULTRASONIC CLEANER

UC-20A

USER MANUAL

Biobase Biodustry(Shandong)Co.,Ltd Version 2018



Preface

Before using this system, please read it carefully and understand the contents of this interface manual, so that the correct use of the system. Keep this manual properly and place it in a convenient location.

Warning: Before operating the unit, be sure to read carefully and fully understand important warnings in the operating instructions.

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1. ACCESSORISE:

1. Main machine 2. Sound proof lid 3. Power lead 4. Mesh basket

2. Applications:

Service line, Electron line, Medicament line, Laboratory, Machine line, Horniness alloy line, Chemistry line, etc

3. Preparation:

- 1. Unpack the packing and check if any part get loose.
- 2. Keep the cleaner under ventilated and dry condition, place it flatly.
- 3. Make sure the plug connection is correct and firm. (Use triplex plug and earth connection is required and safer.)
- 4. It's optional to add certain amount of detergent when needed.

4. Specifications:

Model	UC-20A			
Power	120W			
Capacity	3L			
Frequency	40KHz			
Tank size	240*135*100mm (L×W×H)			
Overall size	270*170*210 mm (L×W×H)			
Set time	0-30minutes			
Set temperature	0℃-80℃			
Heating power	100W			
Power supply	AC220V 50Hz/60Hz			

5. Operation:

5.1 START UP ULTRASONIC FUNCTION:

- 1.Fill stainless steel tank with water
- 2.Plug the cleaner into grounded outlet;
- 3.Press the "TIME+"key for setting 0-30 min working time. Press "TIME-" for reduce the time continuous. Press "Ultrasonic" button to "ON", the cleaner will start working. During working, you will hear the "sizzling" voice ,that means the cleaner running properly. (Do not run the cleaner continuously more than one hour at one time)

5.2 START UP HEATING FUNCTION:

- 1.Set temperature(if need): Press the "TEMP+" key for setting temperature 0°C-80°C. Press the "TEMP "key for reduce temperature.
- 2. Then press the "Heating" button to "ON" begin to heat.

5.3 3. STOP ULTRASONIC PROCESS:

- 1.Press the "Ultrasonic" button to "OFF", the cleaner will stops working, indicator light turn off. And then disconnect the power supply.
- 2. Press the "Heating" butoon to "OFF", the heating function will stop.
- 3.Empty the tank and clean both the outside and inside of the cleaner with clean and dry cloth for next use.

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- △Always unplug and empty the cleaner after using.
- △ Remove the contaminants with moist cloth and water for the tank.
- △ Wipe the covering with dry towel.

5.4 ATTENTIONS:



- a) While the machine is working normally, ultrasonic and tank syntony gives a well-proportioned sound, and no shudder on the surface of the water, yet there is spray made by the tiny bubbles. If there are discontinuous surges, please add or release a little of washing solution in the tank, stopping the surges is good for cleaning the objects.
- b) On the condition of make sure the cleaning object is cleaned, please run the machine discontinuously as far as possible(not more than 30min.), for long-time running causes temperature increment of the case, and speedup the aging of the electronic devices.
- c) Flammable cleaning solution is forbidden.
- d) Do not start the heater nor ultrasonic while the tank is empty.
- e) Prevent water or cleaning liquid from spattering into the case or shaker.
- f) When something is dropped into the tank carelessly, take it out immediately.
- g) Make sure the washing liquid is not hot, and turn the ultrasonic off and pull out the plug, while changing or emptying the tank.
- h) Clean the dirt in the tank after using.
- i) Keep the surface of the machine clean.

5.5 WARNING:

- a) Don't plug in the machine with empty tank be sure to fill in proper amount of liquid before plug-in the machine. Otherwise, the heater could be damaged.
- b) Never run the machine with low level of liquid to avoid damaging ultrasonic transducers and heater.
- c) Please note that when you run heater, the liquid in the tank could vapor in the long time period, please keep watching the level of the liquid in the tank



- d) Washing liquid spatters into the shaker results in creepage and short circuit, and burn the wafer as well.
 - e) Electrical abnormity will burn the transistor.
- f) High voltage brings damages to the circuit and indicating lights etc.



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