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Report Number: MIC-ASI212814

Audit Date : 15 Jul., 2021

This report is issued by Focus Technology Co., Ltd. (Made-in-China.com) and the supervising inspectorate (TÜV Rheinland) to confirm that:

Company Name	:	**Shenzhen Uni-Medica Technology Co., Ltd.** **深圳联合医学科技有限公司**
Showroom	:	**https://uni-medica.en.made-in-china.com**
Address	:	**Room 409, Building 3 and Room 202, Building 6, Liuxian Cultural Park, Tongle Road, Nanshan District, Shenzhen City, Guangdong Province, China**
Product	:	**PCR Test Reagent, PCR System, Nucleic Acid Extractor, Nucleic Acid Extraction Reagent, Disposable Virus Sampling Tube**

has been on site audited for the Following Scope of Activity

1. General Information
2. Foreign Trade Capacity
3. Product Research & Development Capacity
4. Management System and Product Certification
5. Production Capacity & Quality Control
6. Working Environment
7. Energy Saving and Emission Reduction
8. Photos

Made-in-China.com Audited Supplier

General Comments:

Shenzhen Uni-Medica Technology Co., Ltd. is a manufacturer and trader combined company with 96 employees. It was established in year 2011. The Company located in Room 409, Building 3, Room 202, Building 6, Liuxian Cultural Park, Tongle Road, Nanshan District, Shenzhen City, Guangdong Province, China. The company covers an area of about 1,800 square meters. It has its own brand "UNI-MEDICA". The company has passed ISO9001 and ISO13485 Management System. And got the CE certification. The company has successful foreign trading experience in South America, Europe, Southeast Asia, Africa, East Asia.

Daisy Zhang

Sign for and on behalf of
TÜV Rheinland

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SUPPLIER ASSESSMENT REPORT

Audited Company	Shenzhen Uni-Medica Technology Co., Ltd.
Audited Site:	Room 409, Building 3 and Room 202, Building 6, Liuxian Cultural Park, Tongle Road, Nanshan District, Shenzhen City, Guangdong Province, China

Consigner of Assessment	**Made-in-China.com**		
Audit Type	☒ Initial Audit ☐ Re-audit		
Audit Date	15 Jul., 2021	Verify Report	https://www.verified.chn.tuv.com/en/
Auditor	Dong Wu	Reviewed by	Jiachen Hu

CONTENTS

TÜVRheinland Assessment Service

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Part A: General Information

Section 1: Company Overview

1.1 Legal Validity			
Does the company have a valid business license?	☒ Yes ☐ No ☐ Others	Registration Number	91440300582717668H
Year of established	23 Sep., 2011	Valid Date	23 Sep., 2031
Registered address	Room 202, Building 6, Liuxian Cultural Park (Formerly Known as "Sangtai Science Park"), Liuxiandong Village, Xili Street, Nanshan District, Shenzhen City, Guangdong Province, China		
Actual address	Room 409, Building 3 and Room 202, Building 6, Liuxian Cultural Park, Tongle Road, Nanshan District, Shenzhen City, Guangdong Province, China		
Does the company in abnormal operation status list of industrial and commercial bureau?	No		
Registered capital	RMB 7,978,927		
Name of legal representative	Ms. Yanping Wang		
Business scope	General business projects are: Research and development and sales of scientific instruments, Analytical instruments and precision instruments (excluding medical devices); Research and development of scientific reagents; To invest and establish industries; Internal trade; Research and development of gene-related technology, Gene detection technology, Gene chip and biological pharmaceutical products; Biotechnology development; Health management consulting. (Except for the items prohibited by the above laws, Administrative regulations and the State Council, The restricted items must be licensed to operate), The permitted operating items are: □ class, The production of class 6840 in vitro diagnostic reagents; Class I, Class II, Class III medical devices, Sales of machinery; Sales of II, III in vitro diagnostic reagents.		
1.2 Basic Information			
Contact person	Ms. Shuangle Liao		
Phone number	0086-13352981818	Fax number	Nil
URL/Web address	https://uni-medica.en.made-in-china.com		
Company type	☐ Manufacturer ☐ Trading Company ☒ Combined ☐ Group Corporation		
Type of ownership	☒ Limited Company ☐ Public Company ☐ Foreign joint venture ☐ State-Owned ☐ Private Owner ☐ Wholly foreign-owned enterprises		
Associated company	Nil		
Products manufactured / sold scope	PCR Test Reagent, PCR System, Nucleic Acid Extractor, Nucleic Acid Extraction Reagent, Disposable Virus Sampling Tube		

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1.3 Company Building Information

According to:

☐ Land certificate ☐Real estate certificate

☒Lease agreement ☐Observation Estimated on site

The company area 1,800 square meters
The land occupies square meters.
The offices occupy 1,000 square meters.
The workshops occupy 800 square meters.

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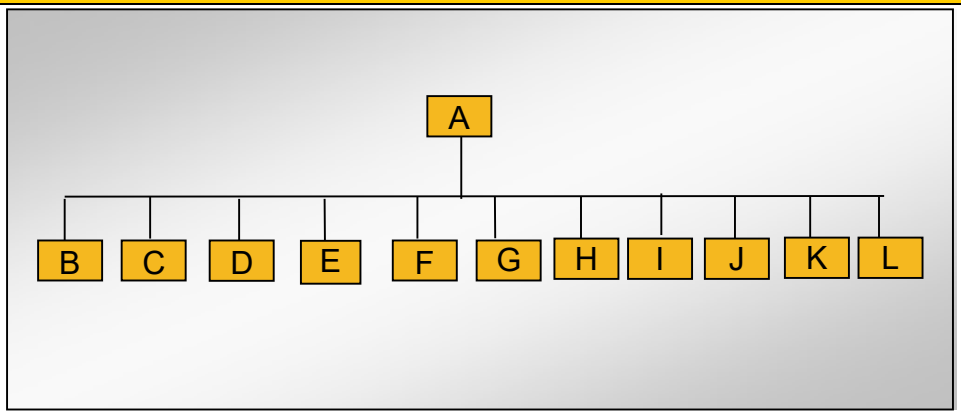
Section 2: Human Resources

2.1 Company Chart



2.2 Explanation of Code and Employee Details

Code	Department	Number of employees
A	GM	1
B	Sales Dept.	33
C	Financial Dept.	2
D	Purchasing Dept.	2
E	R & D Dept.	23
F	Production Dept.	12
G	Admin. Dept.	2
H	Marketing Dept.	3
I	Commercial Dept.	4
J	Clinical Medicine Dept.	5
K	Quality Dept.	6
L	Warehouse Dept.	3
	Number in total:	96

2.3 Key Staff

Title	Full name	Education	Working experience for this trade / total experience
GM	Ms. Yanping Wang	Undergraduate	14/17 Years

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Part B: Foreign Trade Capacity

Section 1: Export Overall Situation

1.1 Export Overall Situation	
Does the company have a valid Import and Export license?	☒ Yes ☐ No
The import and export enterprise code.	91440300582717668H
The number of foreign trading staff with relevant trading experience.	☐ within 1 year staff ☒ 1-5 years 1 staff ☒ 6-10 years 2 staff ☒ over 10 years 4 staff Total 7 staff
The language freely used by foreign trade staff	☒ English ☐ others:
Annual revenue of previous year	Confidential
Annual export revenue of previous year	Confidential
Estimated export revenue for this year.	Confidential
Overseas agent / branch	☐ Yes ☒ No
Nearest port	Shenzhen Port
Acceptable quotation terms	☒ FOB ☒ CIF ☒ CFR
Acceptable payment terms	☒ LC ☒ T/T ☒ D/P ☒ PayPal ☒ Western Union ☒ Small-amount payment
Average lead time (Peak Season)	☒ within 15 workday ☐ one month ☐ 2-3 months ☐ 4-6 months ☐ 6-12 months ☐ more time
Average lead time (Off Season)	☒ within 15 workday ☐ one month ☐ 2-3 months ☐ 4-6 months ☐ 6-12 months ☐ more time

Section 2: Export Business Capacity

2.1 Market Distribution (please list top three areas)

Market	Main Product	Main client
☐ North America		
☒ South America	PCR Test Reagent, PCR System, Nucleic Acid Extractor, Nucleic Acid Extraction Reagent, Disposable Virus Sampling Tube	Confidential
☒ Europe	PCR Test Reagent, PCR System, Nucleic Acid Extractor, Nucleic Acid Extraction Reagent, Disposable Virus Sampling Tube	Confidential
☒ Southeast Asia/ Mideast	PCR Test Reagent, PCR System, Nucleic Acid Extractor, Nucleic Acid Extraction Reagent, Disposable Virus Sampling Tube	Confidential
☒ Africa	PCR Test Reagent, PCR System, Nucleic Acid Extractor, Nucleic Acid Extraction Reagent, Disposable Virus Sampling Tube	Confidential
☒ East Asia (Japan/ South Korea)	PCR Test Reagent, PCR System, Nucleic Acid Extractor, Nucleic Acid Extraction Reagent, Disposable Virus Sampling Tube	Confidential
☐ Australia		
☐ Domestic		
☐ Others		

Section 3: Supplier Management

3.1 Supplier Management		
Item	**Content**	**Observations /Comments**
1	Does the company establish and implement an effective suppliers' assessment procedure?	☒ Have the written procedures and followed records ☐ Have the written procedures but no records ☐ Have relevant records without written procedure ☐ No written procedures or followed records ☐ Other
2	Does the company have an updated list of approved suppliers?	☒ The approved suppliers list was updated in 2020 ☐ Have the written suppliers without approved signature or date. ☐ Provided some suppliers names ☐ No approved suppliers list ☐ Other

Section 4: After-sales Service Capacity

4.1 After-sales Service Capacity		
Item	**Content**	**Observations /Comments**
1	Is there a procedure to conduct random product inspection after final packaging in place?	☒ Have clear standards and written inspection records ☐ No written standards but had inspection reports ☐ Have the procedures but no inspection records ☐ It's not necessary to carry out the inspection ☐ Other
2	Is there a clear procedure for handling customer complaints?	☒ Has the clear procedure and followed records ☐ Has the procedure but no written records. ☐ No written procedures or records. ☐ Other
3	Can the finished/packaged product be traced by lot identification to the appropriate raw materials test reports?	☒ Have the procedures to trace the raw materials. ☐ Can trace main materials ☐ Can trace production date. ☐ Can't trace products ☐ Other
4	Are corrective & preventive actions mechanism established and implemented effectively (including the suppliers/ sub-contractors control, incoming inspection, process control, final inspection and customer complaint)?	☒ Has the clear procedure and followed records ☐ Has the procedure but no written records. ☐ No written procedures or records. ☐ Other

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Part C: Product Research & Development Capacity

1.1 Product Research & Development Capacity	
The amount of R&D and relevant working experience.	☒ within 1year 6 staff ☒ 1-5 years 7 staff ☒ 6-10 years 10 staff ☐ over 10 years staff Total 23 engineers
What is the main job responsibility for R&D engineers?	R&D new products, design drawing with software, and support technology services for producing scene.
Is there any relevant design input, output, review, verification and validation documentation available for auditor to review?	YES
Is there any special software or instrument used by the R&D staffs during the design process of new products? If yes, please list the main software or instrument.	YES, AutoCAD, PCR
Does the company have an effective design change control procedure in place?	YES
Please list the patent certificates and qualification license.	Patent certificates: ZL 2018 2 0451911. X ZL 2017 2 0258746. 1 ZL 2017 2 1521085. 3 ,ZL 2013 2 0686173. 4

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Part D: Management System and Product Certification

1.1 Management System and Product Certification	
Management system certification	☒ISO9001:2015 certificate Certificate Name: ISO9001:2015 Certificate NO.: CN21/42237 Issued by: SGS Issued Date: 16 Mar., 2021 Valid Until: 15 Mar., 2024 Scope: Novel Coronavirus 2019-nCoV nucleic acid assay kit (fluorescent PCR method) has been developed, Manufactured and marketed for the development, Development and marketing of CYP2C19 genotyping assay kit (Fluorescent PCR method) ☒Others Certificate Name:ISO13485:2016 NO.: CN20/42043 Issued by: SGS Issued Date: 16 Mar., 2021 Valid Until: 24 Apr., 2023 Scope: Novel Coronavirus 2019-nCoV nucleic acid assay kit (fluorescent PCR method) has been developed, Manufactured and marketed for the development, Development and marketing of CYP2C19 genotyping assay kit (Fluorescent PCR method)

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Product certification	☒ CE Certificate Name: CE NO.: CMC/CE/2020/22022021.1 Product Name: PCR Kit Model: N/A Standard: 98/79/EEC Issued by: CMC Issue Date: 22 Feb., 2021 Certificate Name: CE NO.: CMC/CE/2020/04092020.4 Product Name: PCR Kit Model: N/A Standard: 98/79/EEC Issued by: CMC Issue Date: 04 Sep., 2020 Certificate Name: CE NO.: CMC/CE/2020/02072020.7 Product Name: Disposable Virus Sampling Tube, Nucleic Acid Extraction Reagent Model: N/A Standard: 98/79/EEC Issued by: CMC Issue Date: 02 Jul., 2019 Certificate Name: CE NO.: CMC/CE/2020/27102020.1 Product Name: PCR Kit Model: N/A Standard: 98/79/EEC Issued by: CMC Issue Date: 27 Oct., 2020 ☐ UL ☐ CCC ☐ RoHS ☐ FCC ☐ Others ☐ NIL
Test reports for raw materials	☐ RoHS ☐ Reach ☐ Others ☒ NIL

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Part E: Production Capacity & Quality Control

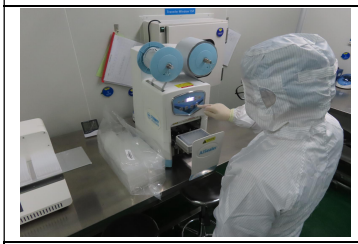
Section 1: Production Capacity

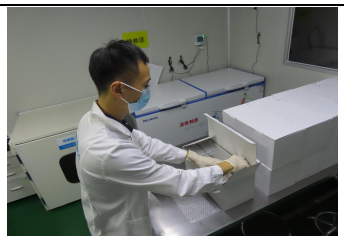
1.1 Production Workflow Chart


Weigh

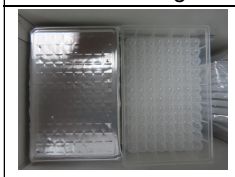

Dosing


Split Charging


Seal


Packaging

1.2 Products Situation (Top three Product Categories)

Product	Price range	Min. order quantity	Top monthly output	Average monthly output	Total in 2020
 PCR Test Reagent	Confidential	Confidential	Confidential	Confidential	Confidential
 Nucleic Acid Extraction Reagent	Confidential	Confidential	Confidential	Confidential	Confidential
 Disposable Virus Sampling Tube	Confidential	Confidential	Confidential	Confidential	Confidential

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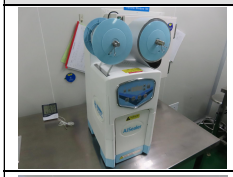
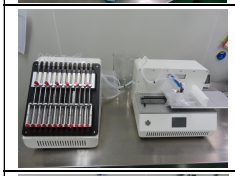
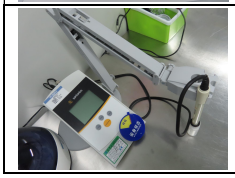
1.3 Main Facilities

Picture	Facility name	Brand or Country/Region of origin	Target Value/machine*day	Quantity
	Sealing Machine	Confidential	Confidential	1
	Racking Machine	Confidential	Confidential	1
	Small Plate Centrifuge	Confidential	Confidential	1
	PH-Meter	Confidential	Confidential	1

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Section 2: Production Process Control

2.1 Production Process Control		
Item	**Content**	**Observations /Comments**
1	Product R&D capacity	☒ Own brand ☒ ODM ☒ OEM
2	Are the environmental conditions, such as tidiness and cleanliness being controlled and suitable for the operation performed?	☒ Very tidy ☐ Normal ☐ Need to improve ☐ Very poor
3	Are the necessary items /documents provided at appropriate location and under control?	☒ Work Instructions /procedures ☐ Workmanship standard /acceptance ☐ Golden sample /Approval sample ☐ Product picture ☐ Verbal by workshop director
4	Are written instructions available for incoming material inspections /testing? Is the relevant record maintained?	☒ Has instructions and uniformly followed ☐ Has instruction but no written records ☐ Materials checked by storage staff
5	Are written inspections /testing instructions available for finished products? Is the relevant record maintained?	☒ Have instructions and uniformly followed ☐ Have instruction but no written records ☐ Finished product checked by packing staff
6	What type of inspection is used for finished products?	☒ Random inspection ☒ Visual inspection ☒ Function inspection ☐ 100% inspection ☐ Visual inspection ☐ Function inspection
7	Are non-conforming units clearly marked/ segregated to prevent accidental dispatch?	☒ Marked and segregated ☐ Segregated but not marked clearly ☐ Not found on site
8	How are the non-conforming units handled?	☐ Repaired and re-inspection ☒ Picked out ☐ Used under control ☐ Others

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Part G: Working Environment

Section 1: Working Environment

1.1 Welfare Benefits		
Item	**Content**	**Observations /Comments**
1	Does the company have effective procedures to verify the age of staff at the time of recruitment?	☒ Has written procedure and keeps adequate age documents of workers ☐ Has written procedure but doesn't follow records ☐ Hasn't written procedure or follows records
2	Do all workers sign employment contracts with the factory?	☒ All workers sign employment contracts ☐ Some workers sign employment contracts ☐ Only management staff sign employment contracts ☐ No staff sign employment contracts
3	Is statutory contribution required for all employees' social insurance (e.g. health insurance, unemployment insurance, accident insurance etc.) paid for by the enterprise?	☒ All workers have social insurance. ☐ Some workers have social insurance ☐ Only management staffs have social insurance ☐ No staff have social insurance
4	Does the company have a clear and effective policy on working hours, rest and vacations? If does, please list it.	☒ All staffs work kept to the policy ☐ Most of the time it keeps to the policy except midseason. ☐ Usually needs overtime. ☐ No relevant records for working hours Describe the working hours: 5 days per week, 8 hours per day
5	Does the company pay extra remunerations for all overtime work?	☒ For all overtime work. ☐ For official holidays ☐ For official holidays except weekend. ☐ No extra remunerations for overtime.
6	Does the company have dormitories for staff? If yes, please describe the condition.	☒ Provide dormitories for all staff ☐ Provide dormitories for workers ☐ Provide dormitories for management staff ☐ No dormitories were provided. Describe the condition: 4 people per room

1.2 Labor Protection		
Item	**Content**	**Observations /Comments**
1	Are there uniforms for all staff in company?	☒ Yes ☐ No ☐ Other
2	Is the emergency medical supplies enough and easily used in workshop?	☒ Yes ☐ No ☐ Other
3	Does the company arrange health and safety training for new workers?	☒ Yes ☐ No ☐ Other
4	Do the workers have the appropriate protective equipment during operation in workshop? Such as gloves, masks.	☒ Yes ☐ No ☐ Other
5	Is there training needed and carried out for fire protection?	☒ Yes ☐ No ☐ Other

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Part H: Energy Saving and Emission Reduction

Section 1: Environmental Management

1.1 Environmental Management		
Item	**Content**	**Observations /Comments**
1	Environmental Management System	☐ ISO 14001 Certificate ☒ Cleaner production management ☐ NIL
2	Environmental Impact Assessment	☐ The Report of Environmental impact assessment is approved by EPA . ☒ NIL
3	Check and Acceptance of Completed Constructive Projects	☐ The Report Completed Constructive Projects Inspection and Acceptance is approved. ☒ NIL
4	"Three Simultaneity" for Environmental protection	☐ The Report of "Three Simultaneity" for Environmental protection Inspection and Acceptance is available. ☒ NIL

Section 2: Water, Gas and Noise Control

2.1 Water, Gas and Noise Control		
Item	**Content**	**Observations /Comments**
1	Water-intaking	☐ Water-intaking license ☐ No water-intaking license ☒ No water taken from natural water body
2	Waste water	☐ Water-draining license or contract ☒ Having carried out waste water treatment before draining ☐ Having carried out waste water monitoring and the result of which being within the standard limit ☐ No detail activities were found
3	Emission to air	☐ Air pollutant emission license ☐ Having carried out air pollutant emission monitoring and the result of which being within the standard limit ☒ No detail activities were found to reduce emission to air
4	Classification and Recycling for solid waste	☒ Having applied trash classification recycling ☐ Having special warehouse for hazardous waste ☐ No detail activities were found
5	Noise	☐ The company carried out noise monitoring and the result of which being within the standard limit one time per year ☒ No detail activities were found

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Part J: Photos

Section 1: Photos of Documents

1.1 Photos of Documents

Description: Business License

Description: Foreign Trade Import and Export Filing Registration Form

Description: Medical Device Production License

Description: Business License Of Medical Devices

Description: ISO13485:2016

Description: ISO9001Certificate

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Description: Trademark	Description: Patent
	
Description: Patent	**Description: Patent**
	
Description: Patent	**Description: CE Certificate**
	

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Description: CE Certificate

EC REP CERTIFICATE

CMC MEDICAL DEVICES & DRUGS SL
NO. CMC/CE/2020/04092020.4

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of
Shenzhen Uni-medica Technology Co.Ltd
Room 202,Block 6th,LiuXian Culture Park, Xili Town, NanShan District,

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.
The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 98/79/EEC in vitro diagnostics as amended.

The products in Annex I was registered in Spanish MOH with number **RPS/2080/2020**

CE

Issued on: 04/09/2020 Valid until: 08/06/2022

Authorised Signatory
CMC Medical Devices & Drugs SL

Description: CE Certificate

EC REP CERTIFICATE

CMC MEDICAL DEVICES & DRUGS SL
NO. CMC/CE/2020/02072020.7

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of
Shenzhen Uni-medica Technology Co.Ltd

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.
The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 98/79/EEC in vitro diagnostics as amended.

The products in Annex I was registered in Spanish MOH with number **RPS/1611/2020**

CE

Issued on: 02/07/2020 Valid until: 08/06/2022

Authorised Signatory
CMC Medical Devices & Drugs SL

Description: CE Certificate

EC REP CERTIFICATE

CMC MEDICAL DEVICES & DRUGS SL
NO. CMC/CE/2020/27102020.1

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of
Shenzhen Uni-medica Technology Co.Ltd

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.
The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 98/79/EEC in vitro diagnostics as amended.

The products in Annex I was registered in Spanish MOH with number **RPS/2466/2020**

CE

Issued on: 27/10/2020 Valid until: 08/06/2022

Authorised Signatory
CMC Medical Devices & Drugs SL

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Section 2: Photos of Company

2.1 Photos of Company and Product Sample

Description: Company Gate

Description: Office

Description: Office

Description: Workshop

Description: Product

Description: Product

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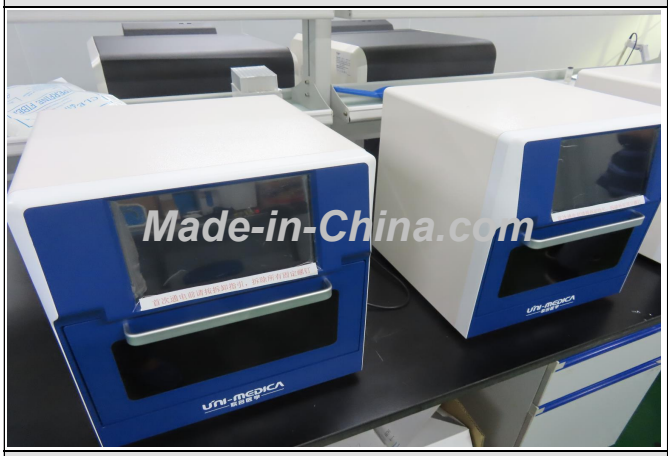
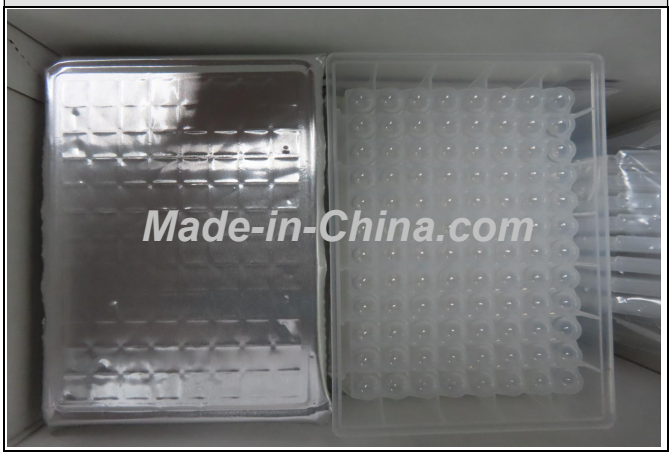
Description: Product	Description: Product
	
Description: Product	**Description: Product**
	

-- End of the Report --