EC REP AGREEMENT

Nº Agreement: 3976220506.EC

Ver: CO-EC-REP-gen-2208

Agreement Expiration Date: 06/05/2027 **Fee:**

Party A:
Zhejiang QL Biotech Co., Ltd. located in Room 501, Building 1#, 178# Chuangye Rd, Qingshanhu Sub-district, Lin'an District, 310000, Hangzhou, China .
(Hereinafter referred to as "COMPANY")

Party B:
CMC Medical Devices & Drugs S.L. Registered place of business at C/ Horacio Lengo no 18, CP 29006, Málaga, Spain. (Hereinafter referred to as "CMC").

1 INTRODUCTION:

This contractual agreement/mandate has been written in accordance with the applicable provisions defined in Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Regulation 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Regulations 90/385/EEC and 93/42/EEC ('MDR') and 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 ('IVDR')('Regulations'), if applicable, to specify the relationship between two parties mentioned above.

Both parties have agreed as follows regarding the handling of all products (hereinafter called "Products") manufactured by COMPANY and sold to the European Economic Area ('EEA' and Turkey).

2 DESIGNATION AND ACCEPTANCE OF THE MANDATE

2.1 COMPANY is a manufacturer of medical devices and/or in vitro diagnostic medical devices not established in a Member State of the European Union, such devices may only be placed on the Union market if the manufacturer designates a sole Authorised Representative in accordance with article 11(1) and defined as in article 2(32) MDR or article 11(1) and 2(25) IVDR.

2.2 COMPANY hereby designates CMC as Authorised Representative, who accepts such designation, as an Authorised Representative for the Business Area and Products set out in Appendix C of this agreement, for placing products on the market. Only Products listed in Appendix C will be subject to the mandate of the Authorised Representative.

2.3 The responsibility of both parties is as stated hereafter in this agreement in relation to the devices that it covers. Appendix A provides an overview of responsibilities. In event of a conflict, the provisions of this agreement shall take precedence over the responsibilities listed in Appendix A, since Appendix A is mainly attached for COMPANY's convenience.

2.4 CMC does not act as an importer or distributor as defined in the MDR/IVDR. Parties explicitly agree that CMC shall not undertake any tasks or responsibilities with respect to the Products listed in Appendix C that would make CMC qualify as an importer or distributor in the meaning of article 13 or 14 MDR or IVDR.

Digitally signed by Perminov Andrei
Date: 2023.04.14 11:40:45 EEST
Reason: MoldSign Signature
Location: Moldova

3 VALIDITY OF THE AGREEMENT

Agreement Expiration Date: 06/05/2027 **Fee:**

3.1 This agreement will enter into effect from the moment the agreement is signed, payment for the service is received and on the condition that COMPANY has made available to CMC a copy of the liability insurance required according to clause 8 of this agreement (see 'Effective Date' date in Appendix C) and remains effective until the "Agreement Expiration Date" stated underneath the header of this document.

3.2 Any changes to this agreement must be approved in writing by CMC and COMPANY by signing a new version of the agreement.

3.3 The service term for each Product starts from the moment the agreement enters into force, and remains effective until the termination of this agreement. Products that need to be added to the list in Appendix C after the moment the agreement entered into force, will be added by means of an addendum signed by both parties. The COMPANY warrants that the Products listed in Appendix C comprise generic device groups.

4 TERMINATION OF AGREEMENT

4.1 This agreement expires at the "Agreement Expiration Date" stated underneath the header of this document, unless terminated by either party with a prior written notification period of sixty (60) days. This agreement is subject to renewal by signing a new version of the agreement with the new agreed expiration date.

4.2 Either party may terminate this agreement upon written notice in the event the other party is in material breach of any obligation under this agreement that is not cured within ten (10) working-days after the breaching party has been notified in writing of the breach and the other party's intend to terminate the agreement.

4.3 In the situation where COMPANY acts contrary to its obligations under the MDR/IVDR, CMC is obligated to terminate this agreement in accordance with article 11(3)(h) MDR/IVDR. Upon becoming aware of such a regulatory non-compliance, CMC will provide written notice to the COMPANY. COMPANY shall answer within three (3) working days and by either i) confirming that it is indeed acting contrary to its obligations under the MDR/IVDR, or ii) explain why its acting is accordance with the MDR/IVDR. When parties disagree on whether COMPANY acts contrary to its obligations under the MDR/IVDR, CMC is entitled to terminate the agreement immediately.

4.4 In the event that liability coverage required by COMPANY in accordance with clause 8 of this agreement, becomes invalid, terminated or is withdrawn and this insurance issue is not fixed within five (5) days, CMC may terminate the agreement forthwith without further notice.

Upon termination of this agreement:

4.5 COMPANY will not place on the market any products bearing the name and address of CMC on its labelling. To this end, COMPANY shall remove all references to CMC from packaging, products, labelling, instructions for use, declaration of conformity and any other marketing material where these details might appear.

4.6 In case of termination in accordance with paragraph 4.3. of this agreement CMC will notify the Spanish Competent Authorities and COMPANY's Notified Body that CMC shall no longer act as the Authorised Representative of COMPANY.

In the event of a change of Authorised Representative, CMC will cooperate with the incoming Authorised Representative in accordance with article 12 MDR/IVDR. The detailed arrangements for a change of Authorised Representative shall be clearly defined in an agreement between COMPANY, CMC, and the incoming Authorised Representative.

5 TASKS TO BE PERFORMED BY CMC ON BEHALF OF COMPANY

5.1 CMC shall comply with requirements imposed on "Authorised Representative" in article 11 of the MDR/IVDR and perform the following tasks:

i. Verify that the EU Declaration of Conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by COMPANY

ii. Keep a copy of the technical documentation, the EU Declaration of Conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, issued in accordance with article 56 MDR / article 51 IVDR, available for the Competent Authorities for a period of at least 10 years after the last device covered by the EU Declaration of Conformity has been placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market;

iii. Comply with the registration obligations laid down in article 31 of the MDR and article 28 of IVDR and verify that COMPANY has complied with the registration obligations laid down in articles 27 and 29 MDR and articles 24 and 26 IVDR;

iv. In response to a request from a Competent Authority, provide that the Competent Authority with all the information and documentation necessary to demonstrate the conformity of a device, in an official Union language determined by the Member State concerned;

v. Forward to COMPANY any request by a Competent Authority of the Member State in which the Authorised Representative has its registered place of business for samples, or access to a device and verify that the Competent Authority receives the samples or is given access to the device;

vi. Cooperate with the Competent Authorities on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by the devices;

vii. Immediately inform the COMPANY about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a Product listed in Appendix C of this agreement;

viii. Terminate this agreement if COMPANY acts contrary to its obligations under the MDR or IVDR.

5.2 By way of derogation from clause 5.1, for Products that are covered by the transitional regime of article 120(3) MDR, the so-called 'legacy devices', not all provisions set out in article 5.1 apply. Generally, the requirements of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices ('MDD') apply to these legacy devices. However, in line with MDCG 2021-25 guidance*: conformity with the MDR article 11(3) (c) - (g) of the MDR is required, reflected under point 5.1(iii) - (vii) of this agreement. Additionally, article 11(7) MDR applies to legacy devices. This means that for legacy devices, the elements described under 5.1(i) – (ii) and 5.1(viii) do not form part of the mandate to CMC unless explicitly otherwise.

*Medical Device Coordination Group, 2021-25 guidance: 'Regulation (EU) 2017/745 - application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC', October 2021.

5.3 Except in cases of legacy devices mentioned in the previous paragraph, CMC shall provide copies of all correspondence related to the tasks described in paragraph 5.1 to the Person Responsible of Regulatory Compliance (PRRC), indicated by COMPANY in Appendix B. COMPANY must therefore have available within their organization at least one person responsible for regulatory compliance who possesses the requisite qualifications in the field of medical devices set out in article 15 MDR / IVDR.

5.4 Except in cases of legacy devices mentioned in the paragraph 5.2. of this agreement, CMC will have permanently and continuously available one person responsible for regulatory compliance (PRRC) who possesses the requisite expertise regarding the regulatory requirements for medical devices in the Union, indicated also in Appendix B.

5.5 CMC will allow the use of its name and address from the Effective Date on for the use with the draft Declaration of Conformity (DoC) and draft device label for the Notified Body conformity assessment application, if applicable. The use of the name of address of CMC will be allowed upon the COMPANY having complied with all applicable requirements in particular the registration obligations, ensuring permanent access to the Declaration of Conformity, technical documentation and, if applicable, a copy of the relevant certificate, and upon the positive outcome of the above verification activities that CMC is mandated to perform on the behalf of the Company which is confirmed.

5.6 Upon request of the Competent Authority, CMC will provide it with a copy of this agreement.

5.7 The communication between CMC and the COMPANY shall be in the English language. Communication or documentation in any other language may be refused by CMC or CMC may charge the COMPANY a reasonable market standard service fee for translation of documents.

6 OBLIGATIONS OF THE COMPANY REGARDING THE AUTHORISED REPRESENTATIVE MANDATE

COMPANY shall enable CMC to perform the tasks described under clause 5 of this agreement.

Agreement Expiration Date: 06/05/2027 **Fee:**

6.1 For clause 5.1(i) – (ii): the COMPANY agrees under article 10(8) MDR/ 10(7) IVDR to provide permanent access to an up-to-date version of the technical documentation to CMC as long as this agreement is in place, and ensures that provided information is true and accurate.

The COMPANY agrees to only place devices on the Union Market after CMC has confirmed verification with the requirements of article 11 MDR/IVDR and after CMC has confirmed that it is able to keep the described documentation available.

6.2 COMPANY shall comply with all the requirements specified in article 10 MDR and article 10 IVDR regarding general obligations of manufacturers. COMPANY warrants that the Products are in conformity with the provision of the MDR/IVDR by affixing the CE marking and including them in CMC's mandate.

6.3 COMPANY shall affix CMC's name and registered address as COMPANY's Authorised Representative on the labels, instructions for use and Declaration of Conformity of the Products listed in Appendix C. The COMPANY shall ensure that the CMC address will only be used in accordance with the requirements of the MDR/IVDR, and not for other purposes.

6.4 For clause 5.1 (iii): COMPANY is required under article 10(7) MDR / 10(6) IVDR to comply with the obligations relating to the UDI system referred to in article 27 MDR / 24 IVDR and with the registration obligations referred to in articles 29 and 31 MDR / 26 and 28 IVDR. COMPANY will inform CMC right after it has met these registration requirements. Only after CMC has confirmed to COMPANY that is has verified the registration, COMPANY is allowed to place its Products on the EEA market.

6.5 For clause 5.1 (iv): COMPANY is required under article 10(14) MDR / 10(13) IVDR to provide a Competent Authority all the information and documentation necessary to demonstrate the conformity of the device, in an official Union language determined by the Member State.

6.6 For clause 5.1 (v): COMPANY is required under article 10(14) MDR / 10(13) IVDR to provide to the Competent Authority of CMC samples of the device free of charge or, where that is not possible, provide access to the device in any other way.

6.7 For clause 5.1 (vi): COMPANY is required under article 10(14) MDR / 10(13) IVDR to cooperate with a Competent Authority, at its request, on any corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices which they have placed on the market or put into service. In this light, COMPANY will on its own turn cooperate with the Competent Authority and additionally, support CMC in case assistance is requested by CMC.

6.8 For clause 5.1 (vii): COMPANY provides CMC confirmation of receipt immediately whenever it has received the complaints and reports from healthcare professionals, patients and users about suspected incidents that have been forwarded by CMC.

Agreement Expiration Date: 06/05/2027 **Fee:**

6.9 For clause 5.1 (viii): in case of termination of the agreement due to COMPANY acting contrary to its regulatory obligations under the MDR/IVDR, COMPANY agrees to accept the termination of the agreement. COMPANY agrees that CMC shall not be liable for contractual or extra-contractual damages resulting from termination of the agreement for this reason.

6.10 According to article 87 MDR and 82 IVDR COMPANY will supply CMC with the relevant information relating to: surveillance procedures, adverse incident notifications, safety corrective actions, devices registration and any other information that allows CMC to cooperate with Market surveillance authorities.

6.11 COMPANY should keep, for all Products listed in Appendix C, the relevant documents in English for at least ten (10) years after the last device has been placed on the market, or in the case of implantable devices, fifteen (15) years the last device has been placed on the market in the EEA in order to be provided to CMC for the purpose to be forwarded to or inspected by the Competent Authority.

6.12 COMPANY should provide CMC with the sales list of Products of last calendar quarter through email to CMC's PRRC before the 10th day of the following months: January, April, July and October. Such duty of the COMPANY will not be waived even though there are no sales in one trimester, therefore COMPANY will provide a declaration of no sales to CMC.

7 ADDITIONAL TASKS PERFORMED BY CMC

Complaints/Incident Reports/Field Safety Corrective Actions;
COMPANY will report serious incidents and Field Safety Corrective Actions (FSCA) involving Products of the COMPANY to the relevant Competent Authority via EUDAMED or the national relevant system. CMC will provide assistance to COMPANY. The PRRC contact persons of each party will be used for communication in relation to such incidents or FSCA.

CMC shall keep a register of any received incidents/complaints/non-conforming products and provide COMPANY with any information upon their request.

8 LIABILITY

8.1 COMPANY will add CMC as an additional insured to its product liability insurance policy on behalf of CMC to cover CMC for potential exposure under this agreement in the proper fulfilment of the duties of CMC, except that the COMPANY need not insure and not protect CMC from liability that results from gross negligence of wrongful acts, omissions or unauthorized activities by CMC which are not performed in favor or objective interest of the COMPANY or results from a substantial breach of this agreement by CMC.

8.2 The COMPANY will provide this additional insured policy before signing this agreement and will continue to do so each subsequent year for the duration of this agreement. Provided that COMPANY fails to fulfil this obligation, COMPANY shall indemnify and hold CMC harmless from any damages, losses, and fines incurred to CMC derived from third parties claims.

8.3 COMPANY's product liability insurance shall cover bodily injury, property damage and loss suffered by users, patients or others caused by a Product manufactured by COMPANY and sold in the Union. The insurance coverage will be proportionate to the risk class, type of device and the size of the COMPANY in accordance with article 10 (16) MDR / 10 (15) IVDR. The insurance shall be in place to provide sufficient financial coverage in respect to the COMPANY's potential liability under Directive 85/374/EEC, without prejudice to more protective measures under national law (article 10(16) MDR / 10 (15) IVDR). Proof of maintaining this insurance and proof that such insurance covers CMC and the Products listed in Appendix C for the EEA market and meets the standards set out in article 10(16) MDR / 10(15) IVDR must be provided to CMC before the signature of this agreement. All insurance coverage provided to CMC shall be maintained by COMPANY for the duration of this agreement, including a run-off coverage to cover all Products manufacturer by COMPANY and sold in the Union for the duration of the agreement and thereafter for as long as these Products bear the name and address of CMC.

8.4 Where the COMPANY conducts clinical investigations in the Union the COMPANY shall be responsible for obtaining and maintaining the insurance coverage prescribed by law.

8.5 The COMPANY shall indemnify, defend and hold CMC, its directors, officers, and employees free and harmless from all claims or liabilities for bodily injury, property damage infringement of third party's right concerning intellectual property (i.e. but not limited to copy right, patent right or competition right) arising or alleged to be arising out of the activities, services or other involvement of Company with respect to any sale or delivery of devices of the COMPANY and resulting from, caused by or alleged to be caused by such devices and shall bear all costs and expenses (excluding attorney's fees incurred by CMC before the assumption of defense by the COMPANY) of defending such claims if the cause of any such action had been a defect already existing or alleged to be existing under European or national binding law at the moment when the device left the control of the COMPANY. This commitment on the part of the COMPANY will be maintained upon conclusion/ termination of this agreement and for as long as claims can still be raised against CMC due to activities performed by CMC in the fulfillment by CMC of the terms of this agreement.

9 REMUNERATION

9.1 The COMPANY agrees to remunerate CMC the amount stated underneath the header of this document (Fee:) for fulfilling its role as the designated sole Authorised Representative. The first remuneration is due on the Effective Date as described in clause 3 of this agreement.

9.2 Bank charges or transaction fees must be covered 100% by the COMPANY. The COMPANY will ensure that all payments are remitted in their totally to the beneficiary.

9.3 Both parties agree that the remuneration does not include fees and/or taxes imposed by European and/or national Competent Authorities. CMC shall not be responsible for the delivery of the certificates or other documentation, samples or other things and all delivery charges shall be fully paid by the COMPANY.

9.4 Additional services including but not limited to free sales certificates, GMDN codes, adding new products to this agreements, technical file reviews, can be provided with separate charges, to be agreed between the parties.

9.5 The payment of the remuneration will be transferred within ten (10) business days upon receipt of each invoice.

9.6 Invoices will be sent in electronic format (PDF) and will reference a purchase order.

9.7 In case COMPANY terminates the agreement at any time no remuneration of fee is due and COMPANY is not entitled to offset any payments due under this agreement against alleged claims. The full remuneration of the following year will be applicable in case the termination by COMPANY is given to CMC within the 60 days prior to the annual renewal date.

9.8 The COMPANY agrees to remunerate CMC at a rate of three hundred fifty Euro (€ 350) per hour, following the cancellation of this agreement solely for any activities which might occur during the transition period between CMC and its (potential) successor (transition period being that of the day the agreement ends and the final complaint stemming from the COMPANY's Products carrying the CMC address).

10 DISPUTES

10.1 Goodwill is the basis of resolving any disputes between parties.

10.2 If any dispute or claim between parties is brought before the court, each party consents to exclusive jurisdiction and venue in the Spanish Courts. The place of fulfilment and domicile is the domicile of CMC.

11 CONFIDENTIALITY

11.1 COMPANY and CMC shall treat with confidentiality any information and document, in any form, disclosed in writing or orally, including the agreement itself.

11.2 Either party will not disclose, in whole or in part, any information to any third party and will not duplicate or publish in any media any documentation received except upon mutual written consent.

11.3 This article will survive the termination of this agreement

Version	Change Description
V1	• First issue of the Agreement between " MANUFACTURER" & CMC
V2	Modify product list. Signed on 28/03/2023

Agreement Expiration Date: 06/05/2027

Fee:

For: Zhejiang QL Biotech Co., Ltd.

Authorized Signature name and position:

Ruan Fang
GM

Date: 28/03/2023

For: CMC Medical Devices & Drugs S.L.

Authorized Signature name and position:

Manuel Mateos
Regulatory Affairs Manager

Date: 28/03/2023

APPENDIX A of the Agreement Nº 3976220506.EC

Summary of responsibilities for convinience purpose:

Responsability	COMPANY	CMC
"COMPANY" shall be responsible for the content of instruction (user's) manuals and shall ensure that English language instruction manuals are available to CMC. "COMPANY" shall ensure that the required local language instruction manuals are provided to the customers.	Yes	No
"COMPANY" shall, in order to allow CMC to fulfil its tasks, ensure that CMC has the necessary documentation permanently available.	Yes	No
Comply with the registration obligations "regarding registration of COMPANY, Authorised Representative and importer" and verify that "COMPANY" has complied with the registration obligations regarding "Unique Device Identification System & Registration of Devices".	Yes	Yes
Cooperate with the Competent Authorities on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices.	Yes	Yes
Cooperating with the regulatory authority and providing it with any information it requires during market surveillance activities.	Yes	Yes
Ensuring that all distributors, importers or responsible for handling "COMPANY" products inside the EU, on note that CMC is the Authorised Representative of "COMPANY" in the EU and they must not pursue on event or negative effect for their products.	Yes	No

EC REP AGREEMENT

Nº Agreement: 3976220506.EC

Ver: CO-EC-REP-gen-2208

Agreement Expiration Date: 06/05/2027 **Fee:**

Responsability	COMPANY	CMC
Ensuring that CMC is the Authorised Representative in EU on labelling of "COMPANY" products, and its name and head office are correctly written.	Yes	No
Forward to "COMPANY" any request by a Competent Authority of the Member State in which CMC has its registered place of business for samples, or access to a device and verify that the Competent Authority receives the samples or is given access to the device.	No	Yes
Immediately inform "COMPANY" and regulatory authority about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated.	No	Yes
In response to a request from a Competent Authority, provide that Competent Authority with all information and documentation necessary to demonstrate the conformity of a device, in an official Union language determined by the Member State concerned.	Yes	Yes
Inform "the Competent Authority and the notified body" in case of the termination of this mandate and the reason for termination.	No	Yes
Keep available a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements at the disposal of Competent Authorities for a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market. In the case of implantable devices, if any, the period shall be at least 15 years after the last device has been placed on the market.	Yes	Yes
Notification of any changes to the necessary information (technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements)	Yes	No
Notification of technical changes to the necessary information (technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements)	Yes	No
Provide a copy of this agreement (mandate) to the Competent Authority, upon request.	No	Yes
Provides the regulatory authority with information on its place of business, the name and position of a responsible person and the COMPANY ("COMPANY") it represents.	No	Yes

CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo Nº18, CP29006, Málaga-Spain
www.cmcmedicaldevices.com

Agreement Expiration Date: 06/05/2027 **Fee:**

Responsability	COMPANY	CMC
Providing the regulatory authority with the information it requires when “COMPANY” seeks authorization to market its devices.	No	Yes
Terminate the mandate if “COMPANY” acts contrary to its obligations under EU Regulation.	No	Yes
Verify that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by “COMPANY”.	Yes	Yes

CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo Nº18, CP29006, Málaga-Spain
www.cmcmedicaldevices.com

Agreement Expiration Date: 06/05/2027 **Fee:**

APPENDIX B of the Agreement Nº 3976220506.EC

PRRC information:

COMPANY:

Name: Ruan Fang

Qualification: General Manager

Email: nickruan@qinglibio.com

CMC:

Name: Manuel Mateos
Qualification: Bachelor's degree in pharmacy
Email: mmateos@cmcmedicaldevices.com

EC REP **AGREEMENT**

Nº Agreement: 3976220506.EC

Ver: CO-EC-REP-gen-2208

Agreement Expiration Date: 06/05/2027 **Fee:**

APPENDIX C of the Agreement Nº 3976220506.EC

Authorized Representative's Business Area:
European Union market

Effective date: Upon signature by both parties and reception of payment **Expiration date:** 06/05/2027

Products covered:

Product Name	Model	REF	CLASS	REGULATION	BASIC UDI DI	Date
Adenovirus Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
AMP One Step Amphetamine Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
BAR One Step Barbiturates Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
BUP One Step Buprenorphine Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
BZO One Step Benzodiazepines Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
C-Reactive Protein Semi-Quantitative Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
COC One Step Cocaine Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
COT One Step Cotinine Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
cTnI Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
D-dimer Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
Dengue IgG/ IgM+Ns1 Combo Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
Dengue IgG/IgM Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
Dengue Ns1 Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract

CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo Nº18, CP29006, Málaga-Spain
www.cmcmedicaldevices.com

EC REP AGREEMENT

Nº Agreement: 3976220506.EC

Ver: CO-EC-REP-gen-2208

Agreement Expiration Date: 06/05/2027 **Fee:**

Product Name	Model	REF	CLASS	REGULATION	BASIC UDI DI	Date
EDDP One Step Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
Ethyl Glucuronide (ETG) Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
Ferritin Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
fFN Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
FOB Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
FYL One Step Fentanyl Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
H. Pylori Ab Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
H. Pylori Ab Rapid Test Device (Whole Blood/Serum/ Plasma)	IHP-401		IVD CLASS B	IVDR - Regulation 2017/746	6976081918100000250WC	Signature of this version
H. Pylori Ab Rapid Test Device (Whole Blood/Serum/ Plasma)	IHP-402		IVD CLASS B	IVDR - Regulation 2017/746	6976081918100000250WC	Signature of this version
H. Pylori Ag Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
H. Pylori Ag Rapid Test Device (Feces)	IHP-601		IVD CLASS B	IVDR - Regulation 2017/746	6976081918100000270WJ	Signature of this version
H. Pylori Ag Rapid Test Device (Feces)	IHP-602		IVD CLASS B	IVDR - Regulation 2017/746	6976081918100000270WJ	Signature of this version
HCG One Step Pregnancy Combo Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
HCG One Step Pregnancy Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
HPV Ag Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract

CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo Nº18, CP29006, Málaga-Spain
www.cmcmedicaldevices.com

EC REP **AGREEMENT**

Nº Agreement: 3976220506.EC

Ver: CO-EC-REP-gen-2208

Agreement Expiration Date: 06/05/2027 **Fee:**

Product Name	Model	REF	CLASS	REGULATION	BASIC UDI DI	Date
HPV IgG/IgM Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
Hs C-Reactive Protein Semi- Quantitative Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
HSV-1 Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
HSV-2 Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
Human Fecal Occult Blood (FOB) Rapid Test Device (Feces)	TFO-601		IVD CLASS B	IVDR - Regulation 2017/746	6976081918100000910X3	Signature of this version
Human Fecal Occult Blood (FOB) Rapid Test Device (Feces)	TFO-602		IVD CLASS B	IVDR - Regulation 2017/746	6976081918100000910X3	Signature of this version
iGFBP-1 Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
Influenza A+B Ag Rapid Test Device (Nasopharyngeal swabs/ Nasal swab)			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
Influenza A+B Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
Influenza A+B/ SARS-CoV-2 Ag Rapid Test Device (Nasopharyngeal swabs/ Nasal swab)			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
K2 One Step Synthetic Cannabis Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
KET One Step Ketamine Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
Malaria pf Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
Malaria pf/pan Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
Malaria pf/pv Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract

CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo Nº18, CP29006, Málaga-Spain
www.cmcmedicaldevices.com

EC REP **AGREEMENT**

Nº Agreement: 3976220506.EC

Ver: CO-EC-REP-gen-2208

Agreement Expiration Date: 06/05/2027 **Fee:**

Product Name	Model	REF	CLASS	REGULATION	BASIC UDI DI	Date
MDMA One Step Ecstasy Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See correspondi ng contract
MET One Step Methamphetamine Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See correspondi ng contract
Microalbmin Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See correspondi ng contract
MOP One Step Morphine Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See correspondi ng contract
MQL One Step Methaqualone Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See correspondi ng contract
MTD One Step Methadone Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See correspondi ng contract
Multi-Drug Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See correspondi ng contract
Multi-Drug Rapid Test 1-Step Cup			IVD OTHERS	IVDD - Directive 98/79		See correspondi ng contract
Multi-Drug Rapid Test key Cup			IVD OTHERS	IVDD - Directive 98/79		See correspondi ng contract
Norovirus GI+GII Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See correspondi ng contract
One Step Multi-Drug of Abuse Test Panel （Urine）	DMP-1X1		IVD CLASS B	IVDR - Regulation 2017/746	6976081918100 000980XQ	Signature of this version
One Step Multi-Drug of Abuse Test Panel （Urine）	DMP-1X2		IVD CLASS B	IVDR - Regulation 2017/746	6976081918100 000980XQ	Signature of this version
One Step Multi-Drug of Abuse Test Panel （Urine）	DMP-1X3		IVD CLASS B	IVDR - Regulation 2017/746	6976081918100 000980XQ	Signature of this version
OPI One Step Opiates Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See correspondi ng contract
OXY One Step Oxycodone Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See correspondi ng contract

CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo Nº18, CP29006, Málaga-Spain
www.cmcmedicaldevices.com

EC REP **AGREEMENT**

Nº Agreement: 3976220506.EC

Ver: CO-EC-REP-gen-2208

Agreement Expiration Date: 06/05/2027 **Fee:**

Product Name	Model	REF	CLASS	REGULATION	BASIC UDI DI	Date
PCP One Step Phencyclidine Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
PPX One Step Propoxyphene Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
Procalcitonin Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
Rota/Adeno combo Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
Rotavirus Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
RSV Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
SARS-CoV-2 Ag Rapid Test Device (Nasopharyngeal swabs/ Nasal swab)			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
SARS-CoV-2 IgG/IgM Rapid Test Device (WB/ P/S)			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
SARS-CoV-2 Neutralizing Antibody Rapid Test Device			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
Strep A Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract
Strep A Rapid Test Device(Swab)	IST-501		IVD CLASS B	IVDR - Regulation 2017/746	6976081918100000120VW	Signature of this version
Strep A Rapid Test Device(Swab)	IST-502		IVD CLASS B	IVDR - Regulation 2017/746	6976081918100000120VW	Signature of this version
Syphilis Rapid Test Device (Whole Blood/Serum/ Plasma)	ISY-401		IVD CLASS B	IVDR - Regulation 2017/746	6976081918100000920X6	Signature of this version
Syphilis Rapid Test Device (Whole Blood/Serum/ Plasma)	ISY-402		IVD CLASS B	IVDR - Regulation 2017/746	6976081918100000920X6	Signature of this version
TB Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See corresponding contract

CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo Nº18, CP29006, Málaga-Spain
www.cmcmedicaldevices.com

Agreement Expiration Date: 06/05/2027 **Fee:**

Product Name	Model	REF	CLASS	REGULATION	BASIC UDI DI	Date
TCA One Step Tricyclic Antidepressants Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See correspondi ng contract
THC One Step Marijuana Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See correspondi ng contract
TML One Step Tramado Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See correspondi ng contract
Troponin I Rapid Test Device(Whole Blood/ Serum/Plasma)	CTI-402		IVD CLASS B	IVDR - Regulation 2017/746	6976081918100 000110VT	Signature of this version
Typhoid Ab Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See correspondi ng contract
Typhoid Ag Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See correspondi ng contract
Typhoid/Para Typhoid Ag Rapid Test			IVD OTHERS	IVDD - Directive 98/79		See correspondi ng contract

Products: 80

The products listed in this Appendix C are included under the agreement 3976220506.EC starting from the date in column <Date>.
Products added before the 01/October/2022 will not state the starting date but the comment <See corresponding contract>.

Unless stated otherwise in the column <Date>, the Products will remain included in the contract until the expiration date of this agreement (6 may. 2027).

For: Zhejiang QL Biotech Co., Ltd.

Authorized Signature name and position:

Ruan Fang
GM

CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo Nº18, CP29006, Málaga-Spain
www.cmcmedicaldevices.com

EC REP AGREEMENT

Nº Agreement: 3976220506.EC

Ver: CO-EC-REP-gen-2208

Agreement Expiration Date: 06/05/2027

Fee:

For: CMC Medical Devices & Drugs S.L.

Authorized Signature name and position:

Ruan Fang

Manuel Mateos
Regulatory Affairs Manager

Date: 28/03/2023

Date: 28/03/2023

CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo Nº18, CP29006, Málaga-Spain
www.cmcmedicaldevices.com