AGREEMENT CONTRATO VERTRAG CONTRAT 合同 계약

EC REP AGREEMENT

Nº Agreement: 2975220127.EC

Ver: CO-EC-REP-202110.V1

Agreement Expiration Date: 14/10/2026. **Fee:**

Party A:
Hangzhou Funworld Biotech Co., Ltd. located in Room 301, Buliding 1#, 136 Zhiyi Rd, Yuhang Sub-district, Yuhang District. (Hereinafter referred to as or "Manufacturer)

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" or "EC REP").

1 Introduction:
This contractual agreement/mandate has been written in accordance with the applicable provisions defined in the Regulation (EU) 2017/745 and the Regulation (EU) 2017/746, 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 "Manufacturer" and sold to EU in accordance with the COUNCIL DIRECTIVE 93/42/EEC (MDD) and/or COUNCIL DIRECTIVE 98/79/EEC (IVD). Regulation (EU) 2017/745 on Medical Devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR). In accordance with the essential requirements set out in Annex I of the Directives, with the latest version of "Guidelines on a Medical Devices Vigilance System" and any other applicable directive(s) and regulation(s).

2 Appointment
WHEREAS, Party A is a manufacturer of medical devices not established in a Member State of the European Union, such devices may only be placed on the European Union market if the manufacturer designates a sole authorized representative.

"MANUFACTURER" hereby appoints CMC as Authorized Representative, who accepts such appointment, as a representative for the "Business Area" and "Product Categories" set out in Appendix A. The responsibility of both parties is as stated hereafter and listed in Appendix B in relation to the devices that it covers.

3 This Agreement shall come into force upon signature and remittance of the payment invoice by the manufacturer and remain effective until expiration date mentioned in first page.
The service term for each Medical Device is starting from first day on which the name of Medical Devices was listed in the APPENDIX A, and remain effective until the termination or cancellation of this Agreement.
This Agreement will be subjected to annual renewal, unless terminated by either party with a prior written notification period 60 days.

4 Termination of agreement
Any modification, termination or cancellation of the agreement must always be done in writing.
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.
Delay in payment of the annual fee for more than thirty (30) days upon MANUFACTURER receipt the invoice, will result in a breach of the Agreement, and will be automatically cancelled without notice period.

Digitally signed by Perminov Andrei
Date: 2023.04.14 11:40:26 EEST
Reason: MoldSign Signature
Location: Moldova

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4,1 Upon termination of this Agreement, CMC shall notify the Spanish Authorities and the Manufacturer's Notified Body that it is no longer the "EC REP" of the Manufacturer. Any termination of the Agreement shall not affect accrued rights or liabilities of either party. Manufacturer agrees not to place any products on the market with the name and address of EC REP after the termination of the agreement. The name and address shall be removed from all products, packaging, labeling, instructions for use, advertising material and the Declaration of Conformity. Upon termination of this agreement in case of changing the Authorized representative, CMC will cooperate in transferring the manufacturer´s files to the newly appointed authorized representative. The detailed arrangements for a change of authorized representative shall be clearly defined in an agreement between the manufacturer, CMC, and the incoming authorized representative including the date of termination of the mandate of the outgoing authorized representative and date of beginning of the mandate of the incoming authorized representative

5 Change Control
- ""MANUFACTURER"" will notify "Authorized representative" of any relevant significant or substantive changes in the products to ensure that maintains updated the regulatory documentation. These changes include amendments to technical documentation, declaration of conformity, EC certification and registration activities in EU market.
- Any changes to the information contained in this agreement must be approved in writing by ""MANUFACTURER"" and "Authorized representative".
- This shall be done by approving a new version of the Agreement.

6 Service scope and Responsibilities of the EC REP:
CMC shall comply with requirements referred to "Authorised representative" in article 11 of EU regulation.
CMC shall provide MANUFACTURER with the following services subject to the type of medical Devices:
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 "MANUFACTURER";
ii. Keep 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 art. 56 of MDR /art. 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 MDR/2017/745 OR art 28 of IVDR /2017/746 and verify that "MANUFACTURER" has complied with the registration obligations laid down in articles 27 and 29 MDR/2017/745 OR art 24 and 26 of IVDR/2017/746;
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 the "MANUFACTURER" any request by a competent authority of the member state in which the authorized 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 devices;

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6,1 vii. Terminate this agreement if the “MANUFACTURER” acts contrary to its obligations under this regulation;
viii. Authorized representatives will have permanently and continuously at their disposal at least one person responsible for regulatory compliance (PRRC) who possesses the requisite expertise regarding the regulatory requirements for medical devices in the Union.

EC REP PRRC Information :
NAME: Manuel Mateos
Qualification: Bachelor's degree in pharmacy
Email: mmateos@cmcmedicaldevices.com

To perform the above services by EC REP, the MANUFACTURER shall:
1)Provide CMC with the list of Medical Devices and any necessary information required for registration at least thirty (30) days before export to the territory;
2) Inform CMC any amendments, updates, changes of MANUFACTURER and/or Medical Devices within one (1) business days upon it occurs;
3) ensure that any information and documents provided to EC REP are true and accurate;
4)actively cooperate with EC Rep on any actions and investigation required by the competent authority.

Provided MANUFACTURER fails to perform the above obligations in article 7. MANUFACTURER shall bear any damages, losses, and fines incurred to CMC.

7 Primary obligations of Manufacturer company:

i. “MANUFACTURER” must comply with all the requirements specified in Article 10 MDR - Regulation 2017/745 or/and article 10 IVDR 2017/746 regarding general obligations of manufacturers.
ii. “MANUFACTURER” shall affix CMC´s name and registered address as the Manufacturer´s EC REP on the labels, instructions for use and Declaration of conformity of the manufacturer´s devices.
iii. “MANUFACTURER” shall provide access to the technical documentation to allow the EC REP to fulfill his obligations.
iv. “MANUFACTURER” shall take an adequate liability insurance to prove sufficient financial coverage (Art. 10 para 16 of the Regulation). A document proving this must be sent to EC REP within thirty (30) days upon the signature of this Agreement.
v. The manufacturer shall notify CMC at any incidents immediately on learning of them.
vi. According to the "Guidelines on a Medical Devices Vigilance System” the manufacturer 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.
vii. MANUFACTURER must have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices.

viii. MANUFACTURER should keep the complete sales list (traceability) of all Medical Devices exporting to the Territory including any OEM products by electrical 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 Territory in order to be provided to Party B for the purpose to be forwarded to or inspected by the competent authority.

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7,1 MANUFACTURER should provide CMC with the sales List of Medical devices of last calendar quarter through email before the 10th day of the following months: January, April, July and October. Such duty of the MANUFACTURER will not be waived even though there are no sales in one trimester, and MANUFACTURER will provide a declaration of no sales to CMC.

MANUFACTURER shall ensure the accuracy and validity of the above-mentioned data and be liable for fines, damages and losses incurred by any omission, delay or conceal of the above submission

ix. "MANUFACTURER" shall keep authorized representative informed in all matters that may be connected to the devices placed on the Territory. At the minimum, the exchange of information concerning paragraphs a) to c) hereunder shall be covered:

a) Safeguard Clause
i. "Where a Member State ascertains that any of the medical devices specified in Appendix A, when correctly used for their intended purpose may compromise the health and/or safety of patients, users or, where applicable, other persons, or the safety of property, it shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service." If the relevant Competent Authority contacts the authorized representative, he should immediately communicate such measures to the manufacturer and advise the company as to the implications of this decision.
ii. When the Commission finds that national measures taken under the Safeguard Clause "are unjustified, it shall immediately so inform the Member State which took the measures and the company or authorized representative". If the relevant Competent Authority contacts the authorized representative, he should immediately communicate such information to the manufacturer and advise the company as to the implications of this decision.

7,2 b) Vigilance
i. In case of an incident and If the relevant Competent Authority contacts the authorized representative, he should immediately communicate such information to the company and advise the company as to the implications of this decision.
ii. The company should ensure that the involved authorized representative is kept informed of incident reports and Field Safety Corrective Actions.

c) Serious adverse events during clinical investigation, i.e. in the premarket phase
i. According to Article 80 of MDR 745/2017 and article 76 of IVDR 746/2017, "all serious adverse events must be fully recorded and immediately notified to all Competent Authorities of the Member States in which the clinical investigation is being performed by the sponsor".
ii. Authorized representative should inform the company of decisions of a Member State in respect of refusal or restriction of the placing the devices specified in Appendix A in the market.

8 Complaints/Incident Reports/Field Safety Corrective Actions;
CMC shall immediately inform "MANUFACTURER" about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated.
If ""MANUFACTURER"" considers or has reason to believe that a device which ""MANUFACTURER"" has placed on the market or put into service is not in conformity with regulation, ""MANUFACTURER"" shall immediately take the necessary corrective action to bring that device into conformity, to withdraw it or to recall it, as appropriate. They shall inform the distributors of the device in question and, where applicable, CMC and importers accordingly.

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8,1 CMC shall keep a register of any received incidents/complaints/non-conforming products and provide "MANUFACTURER" with any information upon their request.
"MANUFACTURER" shall report, to the relevant competent authorities, the following:
(a) any serious incident involving devices made available on the Union market, except expected side-effects which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting;
(b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market, if the reason for the field safety corrective action is not limited to the device made available in the third country.
As a general rule, the period for the reporting shall take account of the severity of the serious incident and timelines referred to in the applicable EU regulation.
""MANUFACTURER"" will investigate all serious incidents/complaints and provide a final report to the relevant competent authorities by the required means.

9 Recall
CMC shall keep a register of recalls and keep "MANUFACTURER" immediately informed of such monitoring and provide "MANUFACTURER" with any information upon their request.
In the event that ""MANUFACTURER"" receives a recall, ""MANUFACTURER"" will forward the recall to "CMC".
""MANUFACTURER"" will investigate all recalls and provide "CMC" with a written report.
"CMC" and "MANUFACTURER" will fully cooperate in providing any data requested to support a recall decision. Such data should be provided as a matter of urgency.

10 Accident Handling
On receiving information of an incident, manufacturers must report immediately after they have established a causal relationship between that incident and their device or that such a causal relationship is reasonably possible, and not later than:

- 2 days in the case of serious public health threats;
- 10 days in the case of death or unanticipated serious deterioration in health which has remained unchanged; and
- 15 days for all other events.

The following vigilance related reports need to be made:

* Individual vigilance report (Article 87 MDR, article 82 IVDR)
* Periodic Summary Report (Article 86 MDR, article 81 IVDR)
* Trend reporting (Article 88 MDR, Article83 IVDR)
* FSCA Report (Article 87-89 MDR, Article 82-84 IVDR)

On receiving information of an incident in its business area, Authorized Representative shall notify to COMPANY immediately upon receiving of incident.
- Upon receiving information of any incident, COMPANY shall perform the necessary analysis of the situation immediately and send the required reports to Authorized Representative according to the requirements of latest version of "Guidelines on a Medical Devices Vigilance System" and Regulations. In that way Authorized Representative can send the reports to the relevant Competent Authority as defined in the version of "Guidelines on a Medical Devices Vigilance System"
- If applicable, based on these reports, COMPANY shall instruct Authorized Representative of the necessary countermeasures to be taken. Authorized Representative shall inform the relevant Competent Authority and customer as required in the countermeasure plan issued by COMPANY.

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11 Technical Documentation

"MANUFACTURER" shall establish necessary procedures to prepare and maintain Technical Documentation including the Declaration of Conformity for the "Product Categories' set out in Appendix A to be able to the comply with the MDD or IVDD and MDR or IVDR requirements.
"MANUFACTURER" shall transfer the agreed Technical Documentation and Declaration of Conformity to Authorized Representative and will maintain always available a copy of the latest update version.
"MANUFACTURER" shall have the responsibility to provide to Authorized Representative any additional documentation as required by the Competent Authority or Notified Body.
"MANUFACTURER" shall be responsible for the content of instruction (user's) manuals and shall ensure that English language instruction manuals are available to Authorized Representative.
"MANUFACTURER" shall ensure that the required local language instruction manuals are provided to the customers.

12 Registration

The registration of persons responsible for placing devices on the market shall comply with the requirements of MDD 93/42/ EEC (art 14) or IVDD 98/79/EEC (art 10) and MDR EU 2017/745 (art 29, 30, 31) or IVDR EU 2017/746 (art 26, 27, 28). The Authorized Representative shall register or notify the products set out in Appendix A to the Competent Authority of the member state in which he has his registered place of business when required by regulations.
"MANUFACTURER" shall have all data allowing for identification of concerned devices (GMDN, UDI).

13 Liability

CMC is not the Manufacturer and as such is not responsible for the design, manufacture, packaging and labeling of a devices. CMC does not affix the Ce – marking to the Maufacturer´s device, nor is it responsible for placing the Manufacturer´s device on the market.
The manufacturer will take out the appropriate insurance to cover CMC potential exposure under this agreement, to that effect the manufacturer will add a vendor´s endorsement to his product liability insurance policy on behalf of CMC.
The manufacturer will send this vendor´s endorsement together with the proof of payment within 30 days of signing this agreement and will continue to do so each subsequent year.
The manufacturer hereby releases and discharges CMC in advance and agrees that it will indemnify and hold CMC harmless against all third parties claims, suits, actions, fines, expenses, attorney´s fees, etc, arising out of any product liability or regulatory claims against CMC under this agreement except for any claims from any grossly negligent or malicious act or omission of CMC in relation to the services provided under this agreement.
Provided MANUFACTURER fails to perform their obligations, MANUFACTURER shall bear any damages, losses, and fines incurred to CMC.

14 Fees:

- Fee accorded in first page.
- Bank transaction fees are the sole responsibility of the payer who has to ensure that all payments are remitted in their totally to the beneficiary. Transaction fees shall not be shared between manufacturer and the beneficiary and shall be covered entirely by the payer.
- CMC shall not be responsible for the delivery of the certificates and all delivery charges shall be fully paid by the manufacturer.
- Extra services including but no limited to Free sales certificates, GMDN codes, technical file reviews, can be provided under separate price quotation.
- The payment will be transferred within ten (10) business days upon receipt of each invoice. Each invoice will normally cover an annual period (12 months).
- Invoices will be sent in electronic format (PDF).

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15 Disputes:
Goodwill is basis of resolve of any disputes.
Nevertheless, this agreement is governed by the laws of Spain and any controverse or claim relating to this Agreement will be resolved by arbitration in Spain.
If for any reason a claim proceeds in court, each party consents to exclusive jurisdiction and venue in the Spanish Courts.

16 Confidentiality
MANUFACTURER and CMC shall treat with confidentiality any information and documents, in any form, disclosed in writing or orally, including this Agreement.
Either parties 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.
This article will survive the termination of this Agreement.

Version	Change Description
V1	• First issue of the Agreement between " MANUFACTURER" & CMC

For: Hangzhou Funworld Biotech Co., Ltd.

Authorized Signature name and position:
Nick Ruan
GM
Date: 28/01/2022

For: CMC Medical Devices & Drugs S.L.

Authorized Signature name and position:

Manuel Mateos
Regulatory Affairs Manager
Date: 28/01/2022

APPENDIX A of the Nº Agreement: 2975220128.EC v1
Authorized Representative's Business Area:
EUROPEAN UNION MARKET

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Product Name	GMDN	Model	REF	REGULATION	CLASSIFICATION
Adenovirus Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
AMP One Step Amphetamine Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
BAR One Step Barbiturates Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
BUP One Step Buprenorphine Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
BZO One Step Benzodiazepines Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
C-Reactive Protein Semi-Quantitative Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
COC One Step Cocaine Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
COT One Step Cotinine Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
cTnI Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
D-dimer Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
Dengue IgG/IgM Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
Dengue IgG/IgM+Ns1 Combo Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
Dengue Ns1 Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
EDDP One Step Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
Ferritin Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
fFN Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS

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

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FOB Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
FYL One Step Fentanyl Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
H. Pylori Ab Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
H. Pylori Ag Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
HCG One Step Pregnancy Combo Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
HCG One Step Pregnancy Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
Hs C-Reactive Protein Semi-Quantitative Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
iGFBP-1 Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
Influenza A+B Ag Rapid Test Device (Nasopharyngeal swabs/ Nasal swab)				IVD - Directive 98/79	CLASS IVD OTHERS
Influenza A+B Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
Influenza A+B/ SARS-CoV-2 Ag Rapid Test Device (Nasopharyngeal swabs/ Nasal swab)				IVD - Directive 98/79	CLASS IVD OTHERS
K2 One Step Synthetic Cannabis Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
KET One Step Ketamine Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
Malaria pf Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
Malaria pf/pan Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS

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Malaria pf/pv Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
MDMA One Step Ecstasy Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
MET One Step Methamphetamine Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
Microalbmin Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
MOP One Step Morphine Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
MQL One Step Methaqualone Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
MTD One Step Methadone Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
Norovirus GI+GII Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
OPI One Step Opiates Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
OXY One Step Oxycodone Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
PCP One Step Phencyclidine Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
PPX One Step Propoxyphene Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
Procalcitonin Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
Rota/Adeno combo Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
Rotavirus Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
SARS-CoV-2 Ag Rapid Test Device (Nasopharyngeal swabs/ Nasal swab)				IVD - Directive 98/79	CLASS IVD OTHERS

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Product Name	GMDN	Model	REF	REGULATION	CLASSIFICATION
SARS-CoV-2 IgG/IgM Rapid Test Device (WB/P/S)				IVD - Directive 98/79	CLASS IVD OTHERS
SARS-CoV-2 Neutralizing Antibody Rapid Test Device				IVD - Directive 98/79	CLASS IVD OTHERS
Strep A Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
TB Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
TCA One Step Tricyclic Antidepressants Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
THC One Step Marijuana Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
TML One Step Tramado Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
Typhoid Ab Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
Typhoid Ag Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS
Typhoid/Para Typhoid Ag Rapid Test				IVD - Directive 98/79	CLASS IVD OTHERS

APPENDIX B: Summary of responsibilities

Obligation	Manufacturer	CMC
“MANUFACTURER” shall be responsible for the content of instruction (user's) manuals and shall ensure that English language instruction manuals are available to CMC. “MANUFACTURER” shall ensure that the required local language instruction manuals are provided to the customers.	Yes	No
“MANUFACTURER” shall, in order to allow CMC to fulfil its tasks, ensure that CMC has the necessary documentation permanently available.	Yes	No

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Obligation	Manufacturer	CMC
Comply with the registration obligations "regarding registration of manufacturer, authorized representative and importer" and verify that "MANUFACTURER" 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 "MANUFACTURER" products inside the EU, on note that CMC is the Authorised Representative of "MANUFACTURER" in the EU and they must pursue on event or negative effect for their products.	Yes	No
Ensuring that CMC is the Authorised Representative in EU on containers of "MANUFACTURER" products, and its name and head office are fully written.	Yes	No
Forward to "MANUFACTURER" 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 "MANUFACTURER" 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 reasons.	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

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Obligation	Manufacturer	CMC
Notification of any changes to the information contained in this agreement.	Yes	Yes
Notification of technical changes.	Yes	No
Provide a copy of this 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 manufacturer ("MANUFACTURER") it represents.	No	Yes
Providing the regulatory authority with the information it requires when "MANUFACTURER" seeks authorization to market its devices.	No	Yes
Terminate the mandate if "MANUFACTURER" 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 "MANUFACTURER".	Yes	Yes

For: Hangzhou Funworld Biotech Co., Ltd.

Authorized Signature name and position:

Nick Ruan

GM

Date: 28/01/2022

For: CMC Medical Devices & Drugs S.L.

Authorized Signature name and position:

Manuel Mateos
Regulatory Affairs Manager

Date: 28/01/2022