Add: Prastgatan 68, 111 29 Stockholm, Sweden
PH: +46 709 988 357 Email: Info@mbgls.com

European Authorized Representative

Service Contract

This European Authorized Representative Service Contract (hereinafter referred to as "Contract") is made as of 3rd November 2021 between **MB Global Service AB**, located at Prastgatan 68, 111 29 Stockholm, Sweden (hereinafter referred to as "EAR"), and **Nanjing Universal Medical Equipment Co., Ltd,** located at No. 288 Qinhuai Avenue, Yongyang Street, Lishui District, Nanjing, China (hereinafter referred to as "Manufacturer").

The EAR and the Manufacturer have agreed as follows with regard to the handling of all products (hereinafter called "Products") manufactured by the Manufacturer and sold to EU in order to comply to the requirements set out in the Regulation (EU) 2017/745 for Medical device or Regulation (EU) 2017/746 concerning in vitro diagnostic medical devices (as per applicability) and latest version of "Guidelines on a Medical Devices Vigilance System".

1. Appointment:

1.1. The Manufacturer hereby appoints the EAR, who accepts such appointment, as their representative for the Products set out in Appendix A.

1.2. The responsibility of both parties is as stated hereafter.

1.3. The Service of the EAR covers the new Regulations for medical devices (EU) 2017/745 and in vitro diagnostic devices (EU) 2017/746.

2. Claim Handling

2.1. The EAR shall notify the Manufacturer about any received claims and any change of laws and regulations related to the Manufacturer's products set out in Appendix A.

2.2. The Manufacturer is the immediate responsible person for the claim handling and regulation compliance.

3. Incident Handling

3.1. On receiving information of an incident, as defined in the Regulation (EU) 2017/745, Regulation (EU) 2017/746 (as per applicability) and MEDDEV 2.12-1 "Guidelines on a Medical Devices Vigilance System", the following procedures shall be applied:

3.1.1. The EAR shall notify occurrence of any incident(s) in the EU to the Manufacturer immediately upon receiving any notification of an incident(s).

3.1.2. Upon receiving information of any incident(s) the Manufacturer shall perform the necessary analysis of the situation immediately and send the incident report to the EAR according to the requirements of latest version of Guidelines on the "Medical Devices Vigilance System". In that way the EAR can submit the report to the relevant Competent Authority as defined in the timescale of the latest version of "Guidelines on a Medical Devices Vigilance System".

3.1.3. If applicable, based on the report, the Manufacturer shall instruct the EAR of the necessary countermeasures to be taken. The EAR shall inform the relevant Competent Authority and customer as required in the countermeasure plan issued by the Manufacturer.

4. Responsibilities on Technical Documentation:

4.1. The Manufacturer shall establish necessary procedures to prepare, maintain and update Technical Documentation including the Declaration of Conformity for the Products set out in Appendix A to be able to comply with the MDR/IVDR requirements.

4.2. The Manufacturer shall transfer the agreed Technical Documentation and Declaration of Conformity to the EAR upon request. The Manufacturer shall have the responsibility to provide to the EAR any additional documentation as

required by the Competent Authority or Notified Body.

4.3. The EAR shall provide a copy of the Contract to the competent authority upon request.

5. Instructions for Use (If applicable)

5.1. The Manufacturer shall be responsible for the content of the instructions for use and/or user's manuals (hereinafter “IFUs”), and shall ensure that the English language IFUs are available to the EAR. If required by the local Competent Authorities, the Manufacturer shall produce the German translation of the IFU at their own cost and responsibility.

5.2. The Manufacturer shall ensure that the required local language IFUs are provided to the customers.

6. Registration

6.1. The EAR 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.

6.2. The Manufacturer shall have all data allowing for identification of concerned devices together with the label and the IFUs available to the EAR upon request by competent authority.

7. Tasks to be performed by the EAR:

7.1. 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 the Manufacturer.

7.2. Keep the technical documentation, the EU declaration of conformity and if applicable, a copy of any relevant certificate, including any amendments and supplements 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.

7.3. Comply with the registration obligations laid down in Art. 31 of (EU) 2017/745 or Art. 28 of (EU) 2017/746 and verify that the Manufacturer has complied with the registration obligations laid down in Art. 27 and 29 (EU) 2017/745 or Art. 24 and 26 of (EU) 2017/746.

7.4. In response to a request from a competent authority, provide 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.

7.5. Forward to the Manufacturer any request by a competent authority of the member state in which the EAR 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.

7.6. 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.

7.7. Terminate the Contract if the Manufacturer acts contrary to its obligations under this regulation.

7.8. The EAR 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.

8. Obligations of the Manufacturer:

8.1. Must comply with all the requirements specified in Art. 10 (EU) 2017/745 or Art. 10 (EU) 2017/746 regarding general obligations of manufacturers.

8.2. Shall procure and maintain at all times during the term of the Contract a Product liability insurance covering the products placed on the European market. This liability insurance should include "EAR" as well. This insurance, however, will not protect "EAR" against liability which results from its unauthorized Activities, wrongful or negligent acts of omission, or breach of the Contract.

8.3. The Contract will not be valid if the manufacturer does not meet this requirement.

9. Other Obligations of the EAR & the Manufacturer:

9.1. The EAR shall provide all documentation and information that a market surveillance authority may require for the purpose of market surveillance.

9.2. The EAR shall rescind his contract with the Manufacturer if the latter does not provide him with the access to the necessary information.

9.3. The Manufacturer shall keep the EAR informed in all matters that may be connected to the devices placed on the market in the EU. At the minimum, the exchange of information concerning paragraphs 10 to 12 hereunder shall be informed.

10. Safeguard Clause

10.1. "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 EAR, they should immediately communicate such measures to the Manufacturer and advise the Manufacturer as to the implications of this decision.

10.2. 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 Manufacturer or the EAR". If the relevant Competent Authority contacts the EAR, they should immediately communicate such information to the Manufacturer and advise the Manufacturer as to the implications of this decision.

11. Vigilance

11.1. In case of an incident and if the relevant Competent Authority contacts the EAR, they should immediately communicate such information to the Manufacturer and advise the Manufacturer as to the implications of this decision.

11.2. The Manufacturer should ensure that the EAR is kept informed of incident reports and Field Safety Corrective Actions.

12. Serious adverse events during clinical investigation

12.1. According to Art. 80 of (EU) 2017/745 and Art. 76 of (EU) 2017/746, "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".

12.2. The EAR should inform the Manufacturer of decisions of a Member State in respect of refusal or restriction of the placing of the devices specified in Appendix A in the market.

13. Territory

The following countries represent The EAR's Business Area: EUROPEAN COMMUNITY TERRITORY

14. Remuneration

14.1. The Manufacturer agrees to remunerate “EAR” an annual fee for the services provided and detailed within this Contract.

14.2. Both parties agree that the above-mentioned remuneration does not include fees and/or taxes imposed by some European Competent Authorities and said fees and/or taxes are the responsibility of the Manufacturer.

14.3. The EAR will charge additional fees in case of customer compliant and investigation. The fees will be charged based on the situation and as per the mutual understanding. Traveling will be as per actual expenses.

14.4. Both parties agree that the above-mentioned annual remuneration assumes that “EAR ”’activities do not include a vigilance event as defined by (EU) 2017/745 and (EU) 2017/746, and further defined in the “Guidelines on a Medical Device Vigilance System” (MEDDEV 2.12-1).

14.5. The handling of a vigilance event that entail notification to an authority or the need of expert opinion being obtained must be pre-approved in writing from the Manufacturer to the EAR prior to the EAR engaging in such additional service. The EAR shall invoice such additional service to the Manufacturer on a separate basis at the rate of 250 € per hour, up to the maximum fee as pre- approved in writing to Regulatory Authority from the Manufacturer.

Add: Prastgatan 68, 111 29 Stockholm, Sweden
PH: +46 709 988 357 Email: Info@mbgls.com

15. Validity of the Contract

Unless otherwise earlier terminated as herein provided, this Contract will have a term of five (5) years, commencing from the date of this Contract as contained in the first paragraph of this Contract. The Contract will extend automatically for another year unless one of the parties cancels it by ninety (90) day's prior to written notice.

16. Place of Fulfilment, Domicile, Jurisdiction

Place of fulfilment and domicile is the domicile of "EAR". This Contract shall be governed by the substantive laws of the Kingdom of Sweden and is subject to the exclusive jurisdiction of the Kingdom of Sweden.

Add: Prastgatan 68, 111 29 Stockholm, Sweden
PH: +46 709 988 357 Email: Info@mbgls.com

Appendix A)

Medical Device Information

Sr. No.	Device Name	Class & Rule	Technical File ID with issue date
1	Disposable Medical Nitrile Examination Gloves	Class I, Rule 1	CE-N001 01.11.2021
2	Disposable Medical Latex Examination Gloves	Class I, Rule 1	CE-L001 01.11.2021
3	Disposable Medical PVC Examination Gloves	Class I, Rule 1	CE-P001 01.11.2021

The devices listed in the Declaration of Conformity are those devices that the EAR is responsible for, both in accordance with the Regulation (EU) 2017/745 and/or (EU) 2017/746 and with this Contract.

Attention is drawn to as per Art. 4 of this Contract, in which the Manufacturer agrees to update this Appendix and the respective DOCs every time an additional device is added to the European device program and to ensure that these devices are included in the Manufacturer's device liability insurance issued to the EAR.

For Manufacture Jerry Gao

For the EAR

Authorized Signatory

Name: Jerry Gao

Designation: Sales Director

Date: 03.11.2021

Authorized Signatory

Name: Johnson Liu

Designation: Manager of Regulatory Affairs

Date: 03.11.2021