europecert
Certification Services

European Authorized Representative
Service Contract

This European Authorized Representative Service Contract of 8 pages (the "Contract") is made as of 12th May 2020, between **EUROPECERT** located at **Alsstr 97, 41063 Mönchengladbach, Germany** (hereinafter referred to as "EAR"), and

C1

Subject of Contract

To market a Medical Device in Europe, a CE Mark is required. To obtain the **CE Mark**, the following Directives must be fulfilled:

Council Directive 93/42/EEC concerning medical devices (MDD 93/42/EEC) in its latest version

As required in Annex I, "Essential Requirements" Article 13.3 of the Directive 93/42/EEC of the European Council dated 14 June 1993, (Official Journal of the European Communities No. L169 /1-43, dated 12 July 1993), the Manufacturer appoints "EAR" to be his Authorized Representative as defined in Article 1 (2.): (j) of the Directive 93/42/EEC in Europe. "EAR" does not act as a sales agent or distributor.

C2

Responsibilities of EUROPECERT

In addition to the activities, "EAR" is responsible for the following:

1. EUROPECERT will accept all possible incidents/near incidents from end users of the medical devices of the Manufacturer. EUROPECERT will also gather information from distributors of the medical devices of the Manufacturer. To fulfil its responsibility the Manufacturer discloses the name and address of the distributors if requested and secures that all his main distributors know the name

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and address of "EAR". The main distributors shall notify the Manufacturer and "EAR" as soon as they become aware of all reportable events as defined in the MDD 93/42/EEC and MEDDEV 2.12-1.

2. EUROPECERT shall inform the competent authorities in accordance with article 14.2 of the MDD, that EUROPECERT has been designated by ANHUI ZHONGNAN AIR DEFENCE WORKS PROTECTIVE CO., LTD. to be its European Authorized Representative established in the community.

3. EUROPECERT is based near Düsseldorf in the State of North Rhine-Westphalia, the competent authority is the district government of Düsseldorf (Bezirksregierung Düsseldorf (Code DE/CA20) and shall cooperate with competent authority and with

4. EUROPECERT will respond to all device related field issues such as (a) complaints (b) near incident (c) incident to the Manufacturer on a timely manner one week for complaints, Four working days for near incidents and Twelve hours in case of incidents.

5. Only if necessary and only for the clarification of a severe incident, will "EAR" obtain expert opinion in the matter, upon prior written approval from the Manufacturer.

6. Following prior notification to the Manufacturer of "EAR"'s impending intentions, "EAR" will report (only as and when necessary) incidents or near incidents with the medical devices of the Manufacturer to the relevant Competent Authority in the EU.

7. EUROPECERT will use its best efforts to procure device(s) that have been the cause of an incident or near incident and return said device(s), (either directly or via customer/distributor), to the Manufacturer for evaluation purposes.

8. Upon prior written request to "EAR" from the Manufacturer in each instance, "EAR" will obtain competent legal advice for the benefit of the Manufacturer.

9. EUROPECERT will use its best efforts to observe all changes in legislation occurring within the European Union concerning Medical Devices and report all such legislation to the Manufacturer.

10. EUROPECERT will provide copies of all correspondence created in the execution of these responsibilities and identification of any "safety officers" appointed to fulfil the responsibilities under the directive, to:

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11. EUROPECERT will take full responsibility for payment of its employees and meet all claims of those employees. It shall act as an independent agent of the Manufacturer.

12. In all cases EUROPECERT liability is limited to gross negligence and wilful violation unless otherwise described in the contract. Moreover, claims regarding punitive damages, liquidated damages and loss of profit are excluded.

The common language of communication between EUROPECERT and the

English.

C3

Responsibilities of the Manufacturer

1. The
agrees to provide "EAR" immediately with all relevant documentation and information regarding the medical devices of the Manufacturer to be offered and sold in the EU. Such documentation and information shall be limited to the information and documentation that is needed for the specific purpose of this agreement.

2. If any European authority or national authority or any binding court decision demands from "EAR" access to the Manufacturer's technical documentation as per the applicable Annex of the MDD 93/42/EEC or any other applicable national or European law, for devices sold in the EU, the Manufacturer agrees to provide such documentation to "EAR" within three (3) days of the Manufacturer's receipt of written notification from "EAR".

3. will
insure "EAR" from any liability incurred by "EAR" in the proper fulfilment of the duties of "EAR" under this Contract, except that the Manufacturer shall not insure nor protect "EAR" from liability which results from gross negligence or wrongful acts or omissions by "EAR" or unauthorized activities by "EAR" which are not done in favour or objective interest of the Manufacturer or results from a substantial breach of this Contract by "EAR".

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4. During the duration of this contract, the Manufacturer will maintain insurance for bodily injury, property damage and loss suffered by users, patients or others caused by a Medical Device manufactured by the Manufacturer and sold in the European Union ("EU"), with such insurance coverage being for a minimum 200 times the value of medical device sold in Europe without any financial involvement (deduction) on the part of "EAR".

5. agrees to provide "EAR" with a list of all entities (e.g. importers, distributors) involved in sales and distribution of the manufacturer's device(s) in Europe. The said list shall include the entity's complete name, address and telephone number. The manufacturer agrees to inform and update "EAR" immediately on new entities entering the manufacturer's sales and distribution configuration.

6. In the event "EAR" proposes that action must be taken by the Manufacturer as demanded by European legislation, and in the event the Manufacturer does not follow such proposal from "EAR", then in such an event "EAR" will have the right to take action on behalf of only "EAR", for the sole benefit of "EAR" and at the sole cost of "EAR", which "EAR" considers necessary in order to protect "EAR" against any liability arising from such decision or action of Manufacturer without prior written approval from the Manufacturer. Should the required action be legally necessary and without other less expensive alternatives, the Manufacturer shall compensate "EAR" for those costs incurred by "EAR" in performance of their functions herein. Notwithstanding the above, "EAR" shall not undertake additional expenses, beyond those necessary on behalf of the Manufacturer, without prior written approval from the Manufacturer.

7. agrees to provide "EAR", within fourteen (14) days of publication, with all revised internal procedures pertaining to the management of customer complaints and for the return of device(s) manufactured by the Manufacturer and sold in the EU.

C4

Commencement of Contract

This Contract shall be effective as soon as both "EAR", and the Manufacturer have signed this Contract, with the signed Contract being exchanged between the parties, and the Manufacturer has provided to "EAR", a copy of the liability insurance required to be obtained by the Manufacturer under the terms of this Contract. "EAR" agrees to accept or reject the liability insurance coverage provided by the Manufacturer within seven (7) days after the receipt by "EAR", of a copy of such liability insurance coverage of Manufacturer.

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C5

Duration and Cancellation of the Contract

1. 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 written notice.

2. This Contract may be terminated at any time by either the "Manufacturer" or "EAR", if there has been a breach of this contract by the other party that is not cured within thirty (30) days after the breaching party has been notified in writing of the breach and the other party's intent to terminate the Contract.

3. If liability coverage required to be obtained and maintained by the Manufacturer becomes invalid, terminated or is withdrawn and in the event such insurance is not replaced or reinstated within five (5) days of such invalidity, termination or withdrawal, then and in both such events, "EAR" may terminate this Contract without further notice.

4. Upon the cancellation of this Contract the Manufacturer agrees not to place any devices on the market with the name and address of "EAR". The name and address shall be removed from all device(s), packaging, labelling, Instructions-for-Use, advertising material and the Declaration of Conformity.

5. Upon termination of this Contract, "EAR" will immediately notify the relevant EU authorities that "EAR" is no longer the "Authorized Representative" of the Manufacturer. Upon said notification, "EAR" shall no longer be responsible or in any way liable for the devices of the Manufacturer sold in the EU, including devices from the Manufacturer that still bear the "EAR" Name and Address in any form, and devices of the Manufacturer that are still in use or circulation within the EU, after the date of termination of this contract.

6. Not withstanding the above, the obligations named in § 4 No. 2 of this contract shall extend at least five years after termination/cancellation of the contract

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C6

Range of Devices

This Contract applies only to the devices of the Manufacturer as listed in C11 of this Contract. The Manufacturer agrees to update C11 in advance (including the Declaration of Conformity) every time an additional device of the Manufacturer is to be sold in Europe, in which case the Manufacturer will provide "EAR" with said update to C11 and ensure that "EAR" will be insured under the Manufacturer's liability insurance coverage for the handling by "EAR" of such additional devices.

C7

Remuneration

1. The Manufacturer agrees to remunerate "EAR" with the annual fees agreed as per the terms discussed and finalized before making this contract.

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.

3. "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. Travelling will be as per actuals.

4. Both parties agree that the above-mentioned annual remuneration assumes that "EAR"' activities do not include vigilance event as defined in the applicable Annex of the MDD 93/42/EEC and further defined in the "Guidelines on a Medical Device Vigilance System" (MEDDEV 2.12-1).

5. The handling of 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 "EAR" prior to "EAR" engaging in such additional service. "EAR" shall invoice such additional service to the Manufacturer on a separate basis at the rate of 120 per hour, up to the maximum fee as pre-approved in writing to Regulatory Authority from the Manufacturer.

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C8

Disclosure (Confidentiality)

1. "EAR" agrees to treat all information and documentation with which they come into contact, with the utmost confidentiality. "EAR" will provide information to third parties only upon prior written consent from the Manufacturer.

2. "EAR" agrees to sign the Manufacturer's Confidentiality Agreement, as part of the implementation of this Contract.

C9

Non-Waiver/Validity

1. Any failure at any time of either Party to enforce any provision of this Agreement shall neither constitute a waiver of such provision nor prejudice the right of the manufacturer or "EAR" to enforce such provision at any subsequent time.

2. The invalidity of any provision of this Agreement shall not abrogate the remaining terms and conditions. The invalid term shall be superseded by a new term which reaches the intention of the parties by agreement of the parties.

C10

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 Federal Republic of Germany and is subject to the exclusive jurisdiction of the **Federal Republic of Germany**.

C11

Medical Device Information covered in this agreement

For the purposes of this Contract, the most current Declaration of Conformity, (at the time of signing and exchanging Contracts), signed by the Manufacturer will serve in addition to the below details

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MEDICAL DEVICE INFORMATION

Device Name : DISPOSABLE MEDICAL MASK
Class & Rule : Class I, Rule 1
Technical File ID with issue date : TCF-VC-PE-20200409; 2020.5.08

The devices listed in the **Declaration of Conformity** are those devices that "EAR" is responsible for, both in accordance with Directive 93/42/EEC and with this Contract.

Attention is drawn to as per C3 of this Contract, in which the Manufacturer agrees to update this C11 and DOC 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 "EAR".

For Manufacture

Authorized Signatory
Name: Hongsheng Chen, Hongsheng Chen
Quality Manager
Date:12.05.2020

For Authorized Representative
EUROPECERT

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Authorized Signatory
Name: Joe Kumar
General Manager
Date: 12.05.2020

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00305992

Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

Formblatt für Medizinprodukte, außer In-vitro-Diagnostika
Form for Medical Devices except In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority			
	Code **DE/CA20**		
	Bezeichnung / Name **Bezirksregierung Düsseldorf, Dezernat 24**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Düsseldorf**		Postleitzahl / Postal code **40474**
	Straße, Haus-Nr. / Street, house no. **Cecilienallee 2**		
	Telefon / Phone **+49-211-4750**		Telefax / Fax **+49-211-4752671**
	E-Mail / E-mail **dez24.mpg@brd.nrw.de**		

Anzeige / Notification			
	Registrierdatum bei der zuständigen Behörde Registration date at competent authority **27.05.2020**		Registriernummer / Registration number **DE/CA20/05-Europecert-15/20**
	Typ der Anzeige / Notification type ☒ Erstanzeige / Initial notification ☐ Änderungsanzeige / Notification of change ☐ Widerrufsanzeige / Notification of withdrawal		
	Frühere Registriernummer bei Änderungs- und Widerrufsanzeige Previous registration number if notification has been changed or withdrawn		
	Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG ☐ Hersteller / Manufacturer ☒ Bevollmächtigter / Authorised Representative ☐ Einführer / Importer ☐ Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG \ Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG ☐ Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV ☐ Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG		

Anzeigender / Reporting organisation (person)			
	Code **DE/0000048517**		
	Bezeichnung / Name **Europecert**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Mönchengladbach**		Postleitzahl / Postal code **41063**
	Straße, Haus-Nr. / Street, house no. **Alsstr. 97**		
	Telefon / Phone **021619908831**		Telefax / Fax
	E-Mail / E-mail **support@europecert.eu**		

Hersteller / Manufacturer			
	Staat / State **CN**		
	Ort / City **Anhui**		Postleitzahl / Postal code **246300**
	Straße, Haus-Nr. / Street, house no. **Qianshan Comprehensive Economic Development Zone, Anhui Province**		
	Telefon / Phone **+86-18955695932**		Telefax / Fax
	E-Mail / E-mail **342818825@qq.com**		

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9) **Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG**			
	Bezeichnung / Name **Soio Augustine George**		
	Staat / State **Indien**		Land / Federal state
	Ort / City **Bangalore**		Postleitzahl / Postal code **560029**
	Straße, Haus-Nr. / Street, house no. **S8, JJ Park, 4 Cross, BhavaniNagar, S.G Palya**		
	Telefon / Phone **+919945912081**		Telefax / Fax
	E-Mail / E-mail **sg@i3cglobal.com**		

Vertreter / Deputy (optional)			
	Bezeichnung / Name		
	Telefon / Phone		Telefax / Fax
	E-Mail / E-mail		
	☒ Erstanzeige / Initial notification ☐ Änderungsanzeige / Notification of change		

Medizinprodukt (Erstmaliges Inverkehrbringen) / Medical device (First placing on the market)	
	Klasse / Class ☒ I ☐ I - steril / sterile ☐ I - mit Messfunktion / with measuring function ☐ I - steril und mit Messfunktion / sterile and with measuring function ☐ IIa ☐ IIb ☐ III ☐ III - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012 manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012 ☐ Aktives implantierbares Medizinprodukt / Active implantable medical device ☐ Aktives implantierbares Medizinprodukt - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012 Active implantable medical device - manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012
	App (Software auf mobilen Endgeräten) ☐ ja / yes ☒ nein / no
	Nummer(n) der Bescheinigung(en) / Certificate number(s)
	Handelsname des Produktes / Trade name of the device **Disposable Medical Mask**
	Produktbezeichnung / Name of device **Mundschutzmaske**
	Nomenklaturcode / Nomenclature code **16-366**
	Nomenklaturbezeichnung / Nomenclature term **Mundschutz**
	Kategoriecode / Category code **10**
	Kategorie / Category **Produkte zum Einmalgebrauch**
	Kurzbeschreibung deutsch / German short description **Mundschutzmaske zur Reduktion der Übertragung von Krankheitserregern durch Sekrettröpfchen**
	Kurzbeschreibung englisch / English short description **Face Mask to reduce the transmission of diseases through secretion droplets**

Medizinprodukte (Aufbereiten) / Medical devices (Reprocessing)

☐ Semikritische Medizinprodukte / Semicritical medical devices
- ☐ Gruppe A / Group A
- ☐ Gruppe B / Group B

☐ Kritische Medizinprodukte / Critical medical devices
- ☐ Gruppe A / Group A
- ☐ Gruppe B / Group B
- ☐ Gruppe C / Group C

Nummer der Bescheinigung / Certificate number

Sterilisationsverfahren / Sterilisation procedures
- ☐ Dampfsterilisation / Steam sterilisation
- ☐ Gassterilisation / Gas sterilisation
- ☐ Strahlensterilisation / Radiation sterilisation
- ☐ andere / others

Angewandtes Verfahren / Applied procedure

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
I affirm that the information given above is correct to the best of my knowledge.

Ort
City **Mönchengladbach**

Datum
Date **2020-05-19**

Name **Joe Kumar**

Unterschrift
Signature

Bearbeitungsvermerke / Processing notes
Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority

Bearbeiter / Person responsible	Telefon / Phone
Frau Jennifer Kraus	**0211/475-4148**