BIOMEDICAL INSTRUMENTS Biomedical Instruments Co., Ltd.

Self-Declaration

We, **Biomedical Instruments Co., Ltd.**, located at Room 4C1, F2.6 Tianzhan Building, Tianan Chegongmiao Industrial Zone, Futian District, Shenzhen 518042 China, as the manufacturer of below devices as listed, hereby declare with sole responsibility that our company and below devices meet the following conditions.

(a) The EC certificate of below devices listed issued by notified body in accordance with Directive 93/42/EEC from 25 May 2017 was still valid on 26 May 2021 and has not been withdrawn afterwards;

(b) The devices listed below continue to comply with Directive 93/42/EEC;

(c) There are no significant changes in the design and intended purpose for the devices listed below;

(d) The devices listed below do not present an unacceptable risk to the health or safety of patients, users, or other persons, or to other aspects of the protection of public health;

(e) Our company has put in place a quality management system in accordance with Article 10(9) of Regulations (EU) 2017/745 on 01 May 2021;

(f) Our company has signed a written agreement with notified body in accordance with Section 4.3, second subparagraph, of Annex VII of Regulations (EU) 2017/745 on 02 November 2021.

Therefore, even though our EC certificate of the devices as listed issued by notified body in accordance with Directive 93/42/EEC will expire on 31 March 2023, according to the REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2023, the EC certificate shall remain valid after the end of the period indicated on the certificate until 31 December 2028.

Devices : Holter System, PC ECG, Ambulatory Blood Pressure System

Classification : IIa according to Rule 10

Notify Body : TÜV SÜD Product Service GmbH
Ridlerstr 65 80339 Munich Germany.

EC Certificate Number : G2 18 01 64548 017
Valid until : 2023-03-31
Extension of the transitional period until: 2028-12-31

BIOMEDICAL INSTRUMENTS

Biomedical Instruments Co., Ltd.

Notify Body identification Number : CE0123

EU Representative : Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

Issued by : Biomedical Instruments Co., Ltd.
Room 4C1, F2.6 Tianzhan Building, Tianan Chegongmiao
Industrial Zone, Futian District, Shenzhen 518042 China.

Authorized Signature ..... / General Manager

Place, Date : Shenzhen / 2023-03-22

Appendix:
1. EC Certificate
2. MDR Agreement with Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 18 01 64548 017

Manufacturer: **Biomedical Instruments Co., Ltd.**
Room 4C1, F2.6 Tianzhan Building
Tianan Chegongmiao Industrial Zone
Futian District
518042 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: **Shanghai International Holding Corp. GmbH (Europe)**
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies): **Holter System, PC ECG, Ambulatory Blood Pressure System**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: SH18322EXT01

Valid from: 2018-04-01
Valid until: 2023-03-31

Date, 2018-02-02

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate
Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 18 01 64548 017

Facility(ies):

Biomedical Instruments Co., Ltd.
Room 4C1, F2.6 Tianzhan Building, Tianan
Chegongmiao Industrial Zone, Futian District,
518042 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

Product Service

Add value.
Inspire trust.

TÜV SÜD Product Service GmbH · Ridlerstrasse 65 · 80339 Munich · Germany

Ms. Ya Chen
Biomedical Instruments Co., Ltd.
Tianan Chegongmiao Industrial Zone
Room 4C1, F2.6 Tianzhan Building
Futian District
518042 SHENZHEN
PEOPLE'S REPUBLIC OF CHINA

Phone: 086-0755-83732921

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
64548	PS-MHS-IBSC Mira Heymann			2021-11-03	1 of 1

MDR/IVDR Framework Agreement – Your signed Framework Agreement (Ref. No.: 64548)

Dear Ms. Chen,

Thank you for providing the signed Framework Agreement.

We countersigned them, archived our original and are handing over yours. Your future orders for Conformity Assessment Services will be processed under your FWA Ref. No. 64548.

We thank you for your interest in our services and your trust in TÜV SÜD and will be happy to answer any questions you may have using the known contact details.

Kind regards,

Mira Heymann
TÜV SÜD Product Service GmbH

Ref. No. 064548

FRAMEWORK AGREEMENT
FOR THE PROVISION OF CONFORMITY ASSESSMENT SERVICES UNDER MDR/IVDR

between

TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, HRB 85742

– "**TÜV SÜD PS**" –

and

Biomedical Instruments Co., Ltd.

Room 4C1, F2.6 Tianzhan Building, Tianan Chegongmiao Industrial Zone, Futian District, 518042 Shenzhen, P.R.China.

– "**Manufacturer**" –

– **TÜV SÜD PS** and **Manufacturer** shall also each be referred to individually as "**Party**" and jointly as "**Parties**" –

Index

List of Exhibits

Exhibit 1	Testing and Certification Regulation TÜV SÜD Group
Exhibit 2	List of Affiliate(s) of TÜV SÜD PS GmbH
Klicken oder tippen Sie hier, um Text einzugeben.	Klicken oder tippen Sie hier, um Text einzugeben.

Introduction

(A) Whereas **TÜV SÜD PS** is a Notified Body which following Chapter IV of Regulation (EU) 2017/745 ("**MDR**") and/or Regulation (EU) 2017/746 ("**IVDR**") has been designated to perform conformity assessment services.

(B) Whereas **Manufacturer** is desirous to retain from time to time certain Conformity Assessment Services rendered by **TÜV SÜD PS** for its products as specified in a Formal Application and Purchase Order and the relating Order Confirmation.

(C) Whereas Section 4.3 of Annex VII of MDR and Section 4.3 of Annex VII of IVDR provide for a (1) Formal Application of a Manufacturer to be placed with the Notified Body the Manufacturer wishes to entrust with the performance of Conformity Assessment Services and (2) a written agreement to be made between the Manufacturer and the Notified Body entitling the Notified Body to carry out the Conformity Assessment Services in compliance with the rules and regulations as set out by MDR/IVDR.

(D) Whereas **Manufacturer** or his **Authorised Representative** in the name and on behalf of **Manufacturer** may retain such Formal Applications from time to time with **TÜV SÜD PS**.

(E) Whereas the Parties hereto wish to agree in writing on the terms and conditions for the performance of such Conformity Assessment Services in compliance with the MDR and/or the IVDR, as applicable.

Now therefore the Parties hereto agree as follows:

1. Definitions

"**Agreement**" means this Framework Agreement for the provision of Conformity Assessment Services under MDR/IVDR.

"**Applicable Law**" means the regulatory provisions as set out in Regulation (EU) 2017/745 and Regulation (EU) 2017/746 ("**Regulations**") and all relating derogative Regulations, acts, guidelines and national laws relating to the implementation to the Regulations.

"**Affiliate**" means any legal entity controlling, controlled by, or under common control with a Party. For these purposes, "control" shall refer to: (i) the possession, directly or indirectly,

of the power to direct the management or policies of a legal entity, whether through the ownership of voting securities, by contract or otherwise; or (ii) the ownership, directly or indirectly, of at least 50 % of the total voting securities or other ownership interest of the respective legal entity.

"**Application Form**" means the application containing all relevant information for the performance of Conformity Assessment Services as desired by **Manufacturer** or his **Authorised Representative** in the name of and on behalf of Manufacturer.

"**Authorised Representative**" means any natural or legal person established within the European Union who has received and accepted a written mandate from a manufacturer, located outside the European Union, to act on the Manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under the Regulations.

"**Confidential Information**" comprises all technological and non-technological information, including in particular findings and results, technical files, documentation, drawings, plans, specifications, methods, formulae, algorithms, prototypes, information about conditions within the company, strategies, balance-sheet information, know-how, materials and other items, disclosed verbally or in written, electronic, digital or other form to **TÜV SÜD PS** or its Affiliate(s) for the purpose if this Agreement and any Conformity Assessment Contract, and which has been identified as confidential or is confidential in nature.

"**Conformity Assessment Contract**" means the individual Agreement made between **TÜV SÜD PS** and the **Manufacturer** following the procedure as laid out in Section 3.3 of this Agreement relating to the conformity assessment of a product or a group of products as specified in the Application Form, the Purchase Order and relating Order Confirmation.

"**Conformity Assessment Services**" means all services and duties to be carried out by notified bodies as set out in the Regulations, in particular in Section 4.5 of Annex VII of MDR and Section 4.5 of Annex VII of IVDR.

"**Formal Application**" means the binding application duly signed by **Manufacturer** containing all relevant information for the performance of Conformity Assessment Services as desired by **Manufacturer** to be carried out by the **TÜV SÜD PS** always accompanied by a Purchase Order, which upon **TÜV SÜD PS**' acceptance – by way of Order Conformation - shall become the Conformity Assessment Contract.

"**IVDR**" means Regulation (EU) 2017/746.

"**MDR**" means Regulation (EU) 2017/745.

"**Order Confirmation**" means the confirmation submitted by **TÜV SÜD PS** confirming the acceptance of a Purchase Order.

"**Parties**" means **TÜV SÜD PS** and the **Manufacturer** (each of them a "**Party**").

"**Pre-Application**" means the informal request made by way of a Pre-Application as submitted by **Manufacturer** to **TÜV SÜD PS** or the Affiliate of **TÜV SÜD PS** with regard to the provision of certain Conformity Assessment Services.

"**Purchase Order**" means the formal purchase order of the **Manufacturer** accompanying the Formal Application, following the non-binding quotation of **TÜV SÜD PS** accepting the terms and conditions for the performance of the Conformity Assessment Services as set out by **TÜV SÜD PS** in its non-binding quotation.

"**Subcontractor**" means any Affiliate or Third Party engaged by **TÜV SÜD PS** in the performance of Conformity Assessment Services as set out in Section 4.2 of this Agreement.

"**Testing and Certification Regulation**" means the Testing and Certification Regulation of the TÜV SÜD Group, forming an integral part of this Agreement, as attached hereto as **Exhibit 1** and as amended from time to time.

"**Third Party**" means any person or legal entity being not a Party, an Affiliate of a Party or the Authorised Representative.

2. Scope of Agreement

This Agreement sets out the terms and conditions, which shall apply to the performance of Conformity Assessment Services carried out by **TÜV SÜD PS** or through its Affiliate(s) – as listed in **Exhibit 2** and as amended from time to time – for **Manufacturer** in compliance with the Applicable Law.

3. Retention of Conformity Assessment Services

3.1 Pre-Application Procedure

Manufacturer may from time to time request **TÜV SÜD PS** by submitting a Pre-Application, with such content as consistent with Section 4.3 of Annex VII of the MDR or the corresponding provision in Annex VII of the IVDR, to make a non-binding quotation for the rendering of Conformity Assessment Services as following from the Pre-Application. Upon receipt of the Pre-Application **TÜV SÜD PS** will in its own discretion assess whether it will be ready to carry out the services as following from the Pre-Application or not. In case **TÜV SÜD PS** is ready to carry out the services, **TÜV SÜD PS** or its Affiliate(s) in the name and on behalf of **TÜV SÜD PS** will submit a non-binding quotation to **Manufacturer** specifying the terms and conditions for the performance of the requested Conformity Assessment Services, which, however, always shall include the terms and conditions of this Agreement. **Manufacturer** may within its own discretion then decide whether it wishes to retain the services as offered by **TÜV SÜD PS** or not.

3.2 Application Procedure

Manufacturer may from time to time retain Conformity Assessment Services to be performed by **TÜV SÜD PS** as described in a Formal Application consistent with the requirements as set out in Section 4.3 of Annex VII of the MDR or the corresponding provision in Annex VII of the IVDR submitted in writing to **TÜV SÜD PS** or its Affiliate(s). Such Formal Application, however, shall only be final and binding upon the **Manufacturer** if accompanied by a Purchase Order duly made, signed and submitted either in writing or electronically by the **Manufacturer** in accordance with the terms and conditions set out in **TÜV SÜD PS**' relating non-binding quotation. In case no written purchase order has been transmitted together with the Formal Application, the Formal Application shall be regarded as Pre-Application and only become binding once a written Purchase Order compliant with **TÜV SÜD PS**' non-binding quotation has been submitted.

3.3 Confirmation of Formal Application, Conformity Assessment Contract

TÜV SÜD PS will within due course assess the Formal Application and confirm its acceptance of the Formal Application and the relating Purchase Order subject, however, that such Purchase Order has been timely submitted, by way of Order Confirmation, which may

be submitted in writing or electronically at **TÜV SÜD PS**' choice. The Formal Application together with the Purchase Order as confirmed by **TÜV SÜD PS** shall become the Conformity Assessment Contract.

4. General Rules for Performance of Services, Subcontractors

4.1 Conflicting Terms

TÜV SÜD PS will perform the Conformity Assessment Services in compliance with the MDR and/or the IVDR, as applicable, the Testing and Certification Regulation, this Agreement and the Conformity Assessment Contract. In case of contradictions the rules and Regulations of the MDR and/or the IVDR, as applicable, shall prevail, followed by the terms as laid down in this Agreement. Any general terms and conditions of **Manufacturer** shall have no effect even if referenced to in **Manufacturer**'s Purchase Order or any other document.

4.2 Subcontracting

TÜV SÜD PS shall be entitled to entrust its Affiliates as listed in **Exhibit 2** and any Third Party such as external experts, subject the Subcontractor meets the relevant requirements under the MDR and/or IVDR, with the performance of certain Conformity Assessment Services to the extent as permitted by the Applicable Law (i. e. Section 3.4 of Annex VII of MDR and/or Section 3.4. of Annex VII of IVDR).

4.3 Professional integrity and compliance

TÜV SÜD PS will carry out all services under this Agreement and any relating Conformity Assessment Contract as confirmed by **TÜV SÜD PS** with reasonable professional care, the highest degree of personal and professional integrity and in compliance with the Applicable Law in particular as set out in Annexes IX to XI of MDR and/or Annexes IX to XI of IVDR. **Manufacturer** acknowledges that **TÜV SÜD PS** does not owe any success and in particular has no obligation to render any certificate under this Agreement or any Conformity Assessment Contract as confirmed by **TÜV SÜD PS**, but will perform its services hereunder as notified body rendering its assessment and relating conclusions and decisions independently in accordance with the Applicable Law.

5. Special Rules and Obligations, Testing and Certification Regulation

The **Manufacturer** acknowledges that **TÜV SÜD PS** as notified body when carrying out Conformity Assessment Services has specific rights and duties under the Applicable Law in particular as further specified in the Testing and Certification Regulation. **Manufacturer** acknowledges and agrees that compliance with the requirements under the Applicable Law is essential and any act of non-compliance of **Manufacturer** may be regarded as breach of its obligations, which may result in a termination of this Agreement and any Conformity Assessment Contract concluded on the basis of this Agreement including a suspension, restriction or withdrawal of certificates. All further details are specifically set out in the attached Testing and Certification Regulation. Available at: Testing and Certification Regulation of TÜV SÜD Group . In this regard the Parties hereto agree in particular the following:

5.1 Auditing Rights

Manufacturer grants to **TÜV SÜD PS** the auditing rights as set out in the Applicable Law and specified further in the Testing and Certification Regulation.

5.2 Certificates, Duration, Renewal, Suspension, Restriction, Withdrawal

Certifications are rendered in accordance with the Applicable Law for a duration of five (**5**) years maximum. The concrete duration of any certificate rendered is following from the respective certificate. It is the **Manufacturer**'s own responsibility to timely apply for any renewal. Any Formal Application for renewal shall not be placed to **TÜV SÜD PS** or its Affiliate(s) later than nine (**9**) months prior to the expiration of the respective certificate. Any Formal Application for renewal for Implantable Class IIb Devices and Class III Devices, shall not be placed to **TÜV SÜD PS** later than twelve (**12**) months prior to the expiration of the respective certificate. Any certificate might be suspended, restricted or withdrawn by **TÜV SÜD PS** in accordance with the Testing and Certification Regulation, Art. 56 MDR and/or Art. 51 IVDR, as applicable. All further details follow from the Testing and Certification Regulation.

5.3 Information and Cooperation obligations

Manufacturer undertakes to inform **TÜV SÜD PS** in due course with regard to any product, which has been certified by **TÜV SÜD PS**, about all significant changes with regard to the product, manufacturing or other processes, systems, procedures, safety issues, including,

but not limited to the outcome of vigilance reports, or any other item, which might influence the assessment of the products or its safety. **Manufacturer** shall cooperate to its best of abilities with **TÜV SÜD PS** to enable **TÜV SÜD PS** in carrying out its obligations in any certification process initiated following this Agreement and in any post conformity assessment activities to be carried out by **TÜV SÜD PS** in its function as notified body following the Applicable Law. All vigilance information shall be submitted to the following address: **MHS-Vigilance@tuvsud.com**.

5.4 Compliance with the Applicable Law and Testing and Certification Regulation

Manufacturer shall strictly adhere to its obligations resulting from the Applicable Law and the attached Testing and Certification Regulation. **Manufacturer** acknowledges that **TÜV SÜD PS** will in accordance with the Applicable Law from time to time update and amend the Testing and Certification Regulation. Any update or amendment shall become part of this Agreement if submitted to **Manufacturer** by **TÜV SÜD PS** or one of its Affiliates either in writing or electronically, provided that the **Manufacturer** does not object within six (**6**) weeks upon receipt of the update or amendment. **Manufacturer** shall confirm receipt of the update or amendment within three (**3**) business days either in writing or electronically.

6. Remuneration, Payments

6.1 **Manufacturer** shall pay to **TÜV SÜD PS** the remuneration of the services as specified in the Order Confirmation.

6.2 **TÜV SÜD PS** reserves the right, to entrust an Affiliate to raise invoices for services rendered under this Agreement on **TÜV SÜD PS**'s behalf and collect the remuneration for its account. **Manufacturer** agrees that payments of the remuneration can be collected via the account of an Affiliate and **TÜV SÜD PS** will inform **Manufacturer** accordingly when applicable. Unless otherwise specified from time to time by **TÜV SÜD PS**, payments shall be made to **TÜV SÜD PS** or its Affiliate as specified in the Order Confirmation. **TÜV SÜD PS** likewise agrees that the payment of the remuneration for services rendered under this Agreement can be remitted via an Affiliate of the **Manufacturer**. The **Manufacturer** shall inform **TÜV SÜD PS** at latest in the Purchase Order if **Manufacturer** intends to remit the remuneration via an Affiliate of the **Manufacturer**.

6.3 All payments to be made by **Manufacturer** must be paid without any deduction or withholding for or on account of tax, withholding, levy, imposts, duties or other deductions of any kind („**Tax Deduction**“) unless a Tax Deduction is required by law. If a Tax Deduction is required by law to be made in relation to **TÜV SÜD PS**, the amount of the payment due shall be increased to an amount which (after making any Tax Deduction) leaves an amount equal to the payment which would have been due if no Tax Deduction had been required.

6.4 **TÜV SÜD PS** and **Manufacturer** shall cooperate in completing any procedural formalities necessary to legally enable **Manufacturer** to make that payment without a Tax Deduction.

6.5 All payments are a net amount exclusive of any applicable value added tax, sales tax or other similar tax (“**VAT**”). If the payment is subject to VAT, **Manufacturer** shall in addition pay the VAT to TÜV SÜD PS or the competent tax authority, if **Manufacturer** itself is liable for the VAT due.

7. Term and Termination, Consequences of Termination

7.1 Term

This Agreement is made for an initial term of three (**3**) years. It shall renew automatically for further consecutive terms of three (**3**) years each unless terminated by either Party with twelve (**12**) months written notice.

7.2 Termination by **TÜV SÜD PS**

Notwithstanding the foregoing **TÜV SÜD PS** may terminate this Agreement in case **TÜV SÜD PS** notified to **Manufacturer** an update or amendment of the Testing and Certification Regulation and **Manufacturer** objected the updated or amended version to be included into this Agreement. **TÜV SÜD PS** in such case shall exercise its right to terminate this Agreement within three (**3**) months as of receipt of **Manufacturer**’s objection and the termination shall become effective at the end of the month when the termination was received by the **Manufacturer**. Any Conformity Assessment Contracts remain unaffected and the terms and conditions of this Agreement shall further apply to each single Conformity Assessment Contract for its respective.

7.3 Termination by **Manufacturer**

The **Manufacturer** may terminate each Conformity Assessment Contract with twelve (**12**) months written notice.

7.4 Termination for Cause

Any Parties' right to terminate this Agreement and any Conformity Assessment Contract for cause remains unaffected. **TÜV SÜD PS** in particular will be entitled to terminate this Agreement and any Conformity Assessment Contract for cause in case **Manufacturer** does not comply with its obligations under the Applicable Law as further specified in the Testing and Certification Regulation (breach) and any such breach, if curable, is not cured within reasonable time as per **TÜV SÜD PS** request setting the time for cure.

7.5 Written Form

Any termination shall be made in writing in order to be effective.

7.6 Effects of Termination

The termination of this Agreement shall not affect any Conformity Assessment Contract and the terms and conditions of the Agreement shall further apply to each single Conformity Assessment Contract for its duration. The termination of any Conformity Assessment Contract shall entitle **TÜV SÜD PS** to suspend or withdraw the relating certificate(s), unless in case of termination by the **Manufacturer** made in order to change the notified body and further subject to a relating agreement made between the Parties and the new notified body in accordance with the Applicable Law.

8. Insurance, Limitation of Liability

8.1 **TÜV SÜD PS** shall provide for adequate insurance coverage in accordance with the Applicable Law.

8.2 Unless otherwise provided by this Agreement or the Applicable Law **TÜV SÜD PS** shall be liable for breaches of duty in accordance with the statutory provisions, subject, however, that any liability, unless otherwise stipulated herein further below, shall be limited to intent (wilful action) or gross negligence. In the event of simple negligence, **TÜV SÜD PS** shall

only be liable (i) for damage arising from an injury to life, body or health, (ii) for damage arising from a breach of a material contractual duty whose fulfilment is essential to the due and proper performance of the contract in the first place and on the fulfilment of which the other Party to the contract usually relies and may rely; in the latter case liability of **TÜV SÜD PS** is limited to the compensation of damage which was foreseeable and typical when the contract was concluded and shall be limited to one million Euro (**1** Mio €) per incident. The limitation of liability also applies to breaches of duty by or for the benefit of persons for whose fault **TÜV SÜD PS** is responsible pursuant to the statutory provisions and to any personal liability of executive bodies, experts and other employees of **TÜV SÜD PS**.

It does not apply where **TÜV SÜD PS** or any of the persons mentioned above has fraudulently concealed a defect and with respect to claims arising from a guarantee of a specific quality or claims under the German Product Liability Act (*Produkthaftungsgesetz*). This shall not be linked to a change in the burden of proof to the disadvantage of the buyer of **Manufacturer**'s product.

8.3 In case the **Manufacturer** intends to raise claims under this Agreement he shall without delay inform **TÜV SÜD PS** in writing any potential damage and set out the details of the claim.

8.4 With the exception of claims based on tort, where claims for damages are limited under this Section 8, they shall be time-barred after one year following the beginning of the statutory limitation period unless subject to the limitation periods of Article 438 (1) No. 2 or Article 634a (1) No. 2 of the German Civil Code (BGB).

8.5 It is understood and agreed that any certification rendered by **TÜV SÜD PS** under this Agreement does not release the **Manufacturer** from any of its obligations vis à vis third parties with regard to quality and functionalities of any of the certified products. It shall be solely the **Manufacturer**'s responsibility to hold any user and/or patient free and harmless from any damage suffered from defects in the medical device or relating to any breach of duty or non-compliance with duties on the part of the **Manufacturer**.

8.6 If claims are made against **TÜV SÜD PS** for compensation by Third Parties in relation to (alleged) defects in the medical device or breaches of duty or non-compliance with duties by **Manufacturer**, then **Manufacturer** will hold harmless and fully indemnify **TÜV SÜD PS** at the first request and will refund **TÜV SÜD PS** reasonable costs for legal defence and

Manufacturer herewith assigns to **TÜV SÜD PS** and **TÜV SÜD PS** accepts assignment of any relating claim against its liability insurance, unless a legally permissible prohibition of assignment is contained in the insurance contract.

9. Confidentiality

9.1 Each Party shall keep and maintain as confidential all Confidential Information of the respective other Party.

9.2 **TÜV SÜD PS** shall limit access to such Confidential Information to only those members of its employees, its Affiliates and Subcontractors who have to know such Confidential Information for the purposes of fulfilling **TÜV SÜD PS**' obligations under this Agreement provided (i) it has previously bound them by confidentiality and restricted use obligations at least as stringent as those set forth herein, and (ii) is and remains responsible for any breach of the confidentiality and restricted use obligations.

9.3 The foregoing obligation shall not apply to information:

(a) which was lawfully known to **TÜV SÜD PS**, its Affiliate or Subcontractor, other than under an obligation of confidentiality, prior to this Agreement;

(b) which will be made available by **TÜV SÜD PS** to designating authority or have to be made available to any other Notified Body or authority to the extent as required the Applicable Law;

(c) which is or becomes generally available to the public by use, publication or the like, through no fault or omission of **TÜV SÜD PS** or its Affiliate or Subcontractor;

(d) which is disclosed to **TÜV SÜD PS** by a Third Party who has the legal right to disclose Information and that is not under a confidentiality or restricted use obligation, directly or indirectly, towards **Manufacturer.**

(e) which **TÜV SÜD PS** is legally obliged to disclose, especially but not limited to if requested by court or administration or lawfully acting consumers claiming a right to information.

9.4 Each Party hereby specifically acknowledges and agrees that the unauthorized disclosure or use of any Confidential Information of the respective other Party might cause immediate and/or irreparable injury to the disclosing Party and its Affiliates, and that the Parties cannot be adequately compensated for such injury in monetary damages. The receiving Party therefore acknowledges and agrees that, in such an event, the disclosing Party shall be entitled to any temporary or permanent injunctive relief necessary to prevent such unauthorized disclosure or use, or threat of unauthorized disclosure or use, and the respective receiving Party hereby specifically waives any right it might have to file any objection with regard thereto. This consent is supplementary to, and will not prejudice any right or remedy, which is available to the respective disclosing Party under any law or this Agreement.

9.5 Each Party shall be entitled to retain copies of the Confidential Information for legal or contractual archival purposes and to the extent required by the designated authority or the Applicable Law.

9.6 Any pre-existing obligation of confidentiality of the Parties shall not be modified or waived by the Framework Agreement.

10. Data Protection

TÜV SÜD PS shall be prohibited from processing or using any personal data of the **Manufacturer** beyond the scope of this Agreement. **TÜV SÜD PS** is committed to observe the statutory and contractual data protection regulations. This includes technical security measures, reflecting the current state of the art (Art. 32 GDPR), and the employees' obligation to maintain confidentiality when handling personal data.

11. Compliance

11.1 **Manufacturer** confirms its awareness of the TÜV SÜD Code of Ethics available online at: https://www.tuvsud.com/en/about-us/code-of-ethics.

11.2 **Manufacturer** represents and warrants to **TÜV SÜD PS** that neither it nor any of its employees have committed any act in connection with this Agreement that may constitute bribery, nor shall **Manufacturer** or its employees commit such acts in the future.

11.3 In the event of any violation of the provisions in this clause attributable to **Manufacturer**'s fault, **TÜV SÜD PS** shall be entitled to terminate all negotiations and all contractual Agreements with **Manufacturer** or withdraw from such Agreements. In the event that **TÜV SÜD PS** is held liable by any Third Party based on a violation of its undertaking in this clause by **Manufacturer**, **Manufacturer** hereby agrees to indemnify **TÜV SÜD PS** from any such claims. In addition, **Manufacturer** hereby agrees to reimburse **TÜV SÜD PS** for all damages related to such Third Party claim.

12. Applicable Law, Place of jurisdiction

12.1 This Agreement and any relating Conformity Assessment Contract shall be submitted to the applicable material law of the Federal Republic of Germany with exception of the rules of the conflict of laws and United Nations Convention on Contracts for the International Sale of Goods (CISG).

12.2 Exclusive Place of jurisdiction shall be Munich/Bavaria, Germany, with the competence of the local High Court in Munich (LG Munich I). Any court competent hereunder shall have jurisdiction also for all objections and counterclaims.

13. Miscellaneous

13.1 Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable material law, but if any provision of this Agreement is held to be prohibited by or invalid under applicable material law, such provision will be ineffective only to the extent of such prohibition or invalidity without invalidating the remainder of this Agreement. The invalid or impracticable provision will be replaced by a ruling that is as close as possible in economic purpose to the invalid or impracticable provision in a legally effective and practicable form. The same will also apply in the event of any unintended omission.

13.2 The Parties mutually acknowledge that they have participated in the negotiation and preparation of this Agreement. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have drafted the Agreement or authorized the ambiguous provision.

13.3 This Agreement and its attachments constitute the entire Agreement of the Parties respecting the subject matter hereof. In the event of any conflict between these terms and any

Exhibits attached hereto, the terms of this Agreement shall control. No amendment, modification, or supplement of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party unless expressly otherwise stipulated in this Agreement.

14. Handwritten Signature

Munich, 02.11.2021	ShenZhen 2021-10-28
	Place, Date
Stefanie Sagerer	Chen Ya
TÜV SÜD Product Service GmbH Signature of two authorised persons	**Biomedical Instruments Co., Ltd.** Signature of authorised person
Stefanie Sagerer	Ms. Chen Ya
Name in block letters	Name in block letters
Munich, 02.11.2021	
	Place, Date
TÜV SÜD Product Service GmbH Signature of two authorised persons	**Biomedical Instruments Co., Ltd.** Signature of authorised person
MAUERMEIR MICHAEL	
Name in block letters	Name in block letters