MEDCERT Zertifizierungs- und Prüfungsgesellschaft
für die Medizin GmbH
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General Order and

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Payment Conditions

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1. General

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1.1 MEDCERT is engaged in the business of auditing and certifying medical devices and quality management systems in accordance with the recognized standards, regulations and statutory provisions and their guidelines.

1.1 MEDCERT 遵照公认的标准、法规和法律规定及其指南文件，专门从事医疗器械和质量管理体系审核和认证业务。

1.2 The Principal shall recognize the Instructions for the Certification of Medical Devices and Quality Management Systems, MEDCERT's General Order and Payment Conditions as well as the price list in their current versions. The Principal hereby acknowledges these documents.

1.2 委托方应清楚了解有关医疗器械与质量管理体系认证以及 MEDCERT 的一般订单和付款条件及其当前版本中价格单的说明。委托方在此承认这些文件。

2. Quotations

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Quotations always relate to the information available at the time of preparation. Cost estimates shall be regarded as price recommendations. Orders placed without having received a quotation shall be charged at cost and in line with the price list in its current version.

报价始终与准备报价时可用的信息有关。费用估算应视作价格建议。对于未收到报价而下发的订单，应按成本收取费用，并应与其当前版本的价格单保持一致。

3. Order Execution

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3.1 Orders accepted by MEDCERT shall be executed in accordance with recognized standards and rules as well as with due observation of the statutory and administrative regulations valid at the time of order execution.

3.1 MEDCERT 受理的订单在执行中应遵守公认的标准和惯例，并全面遵守订单执行时有效的法定规定和行政法规。

3.2 MEDCERT shall not assume any warranty for the correctness of the standards, guidelines and programs representing the basis for inspections unless explicitly otherwise agreed upon.

3.2 除非另外协商明确达成一致意见，否则 MEDCERT 对于检验所依据标准、指南文件和程序的正确性不予承担责任。

3.3 MEDCERT shall not be responsible for the correct performance of items inspected with respect to their technical safety unless explicitly otherwise agreed upon in the order content.

3.3 除非在订单内容中另外明确达成一致意见，否则 MEDCERT 对待检验物品在技术安全方面功能是否正常不予承担责任。

3.4 The Principal shall submit to MEDCERT in due time all necessary documents such as the documentation on the quality management system and product documentation, incl. drawings, plans, test samples, calculations and certificates and shall at any time provide any order-related information in order to make the necessary preparations for inspections prior to their commencement. The Principal bears the sole responsibility for accuracy and authenticity of the submitted documents. The Principal assures MEDCERT that the submitted documents refer to the existing product. Otherwise, MEDCERT shall be entitled to withdraw from the contract.

3.4 委托方应及时向 MEDCERT 提交所有必要文档，例如质量管理体系文档和产品文档，包括图纸、示意图、测试样本、校准和证书，并且应随时提供任何与订单相关信息，以在检验开始前做好必要的准备工作。委托方独立承担对提交文件准确性和真实性的责任。委托方保证向 MEDCERT 所提交的是真正现有产品的文件。否则，MEDCERT 有权撤销合同。

3.5 MEDCERT shall be entitled to make copies of any documents to be made available to it and having an importance for the execution of the order and file such copies in its own records.

3.5 对于因执行订单所需提供给 MEDCERT 的任何文档，MEDCERT 有权制作副本并将其记录在自己的记录中。

3.6 The Principal shall ensure that the medical devices and/or the quality management system always comply with the current certificates. The Principal must immediately inform MEDCERT in writing of

incidents relating to the product assessed for conformity and recalls from the market or planned changes.

3.6 委托方应确保医疗器械和/或质量管理体系始终与当前认证相符。委托方必须立即将评估合格的产品以及从市场召回或计划变化有关的事件以书面形式通知 MEDCERT。

3.7 The Principal shall support MEDCERT in the certification and surveillance of the medical devices and/or quality management system. This also includes unannounced inspections by MEDCERT at the Principal's location, or the location of critical subcontractors and crucial suppliers, which involve the performance of tests and inspections by MEDCERT or an authorized third party to control the correct function of the quality management system.

3.7 委托方应在医疗器械和/或质量管理体系认证和监督过程对 MEDCERT 予以支持。这也包括 MEDCERT 对委托方的工厂或关键分包商和关键供应商的工厂进行突击检查。该突击检查涉及 MEDCERT 或授权第三方执行测试和检查，以对质量管理体系的正确运作进行监控。

3.8 The assessment process includes an assessment of the design documentation for the relevant product(s) on a representative basis, an inspection of the Principal's facilities and, if sufficient reasons exist, the facilities of critical subcontractors or crucial suppliers. The Principal must contractually ensure that MEDCERT shall receive access to the premises of the respective company premises with its essential critical subcontractors or crucial suppliers. As part of these activities, the Principal shall ensure that all documents, information, inspections and evaluations are submitted as requested by MEDCERT.

3.8 评估过程包括在代表性的基础上对相关产品设计文档的评估、对委托方工厂的检查以及在理由充分的情况下对关键分包商或关键供应商工厂的检查。委托方必须遵照合同，确保 MEDCERT 有权进入各公司的处所以及其关键分包商或关键供应商的处所。作为这些活动的一部分，委托方应确保根据 MEDCERT 要求提交所有文档、信息、检验和评估。

3.9 Certification and surveillance in accordance with Directive 93/42/EEC involves the assessment of technical documentation of the generic device group (class IIb) and device subcategory (class IIa) for compliance with the requirements specified by Directive 93/42/EEC.

3.9 根据指令 93/42/EEC 进行的认证和监督涉及到对一般器械组（IIb 级）和器械子类（IIa 级）技术文档的评估，以检查其是否符合指令 93/42/EEC 规定的要求。

3.10 MEDCERT shall, for its own purposes, store data concerning the business correspondence with the Principal in a data processing system. Personal data shall be processed exclusively for MEDCERT's own purposes. In order to fulfil the requirements set forth in the Annex to Section 9 of the Federal Data Protection Act MEDCERT has taken technical-organizational measures which warrant the security of data and data processing operations security. The employees entrusted with the processing of data shall be bound to the Federal Data Protection Act and shall be obliged to observe any data protection regulation. The Principal is aware that their data shall be electronically recorded, stored and processed for order processing and order management purposes. ThePrincipal consents to this recording, storage and processing as part of order processing in accordance with Sections 4, 4a of the Federal Data Protection Act.

3.10 MEDCERT 应将与委托方之间业务通信的相关数据存储在数据处理系统中，以备自己使用。个人数据应仅用于 MEDCERT 自身目的。依照德国联邦数据保护法 (Federal Data Protection Act) 第 9 节附录中的要求，MEDCERT 已采取技术组织措施，保证数据安全和数据处理操作过程的安全。执行数据处理工作的员工受到德国联邦数据保护法的约束并有义务遵守任何数据保护法规。委托方清楚了解，基于订单处理和订单管理之目的，其数据应通过电子方式进行记录、存储和处理。委托方同意根据德国联邦数据保护法第 4 节 4a 的要求将此类记录、存储和处理作为订单处理的一部分。

3.11 MEDCERT, its employees and any external auditors/experts employed by MEDCERT shall without prior authorization not be entitled to use or disclose business and trade secrets of which they become aware during the execution of their work towards third parties.

3.11 未经事先授权，MEDCERT、MEDCERT 的员工及任何外部审核师/专业人士均无权使用或披露其在为第三方执行工作期间获知的业务秘密和商业秘密。

3.12 MEDCERT shall be entitled to have its services partly rendered by subcontractors carefully selected and regarded as qualified by MEDCERT following prior approval by the Principal.

3.12 委托方事先批准后，MEDCERT 应有权使用分包商所提供之部分服务，这些分包商经过慎重选择并且符合 MEDCERT 的资质要求。

3.13 MEDCERT shall reserve the copyright to the inspection results, certificates, expert's opinions etc. compiled and drawn up by it.

3.13 MEDCERT 应对自行编制和拟定的检查结果、认证、专家意见等内容保留其版权。

3.14 The Principal shall allow employees or representative of the accrediting, designating and monitoring body to carry out observed audits in any of the Principal's facilities as well as those of their critical subcontractors or crucial suppliers, if requested and necessary.

3.14 如果要求且有必要，委托方应允许认证、指定和监督机构的员工或代表在委托方任何工厂以及委托方关键分包商或重要供应商的工厂执行监督审核。

3.15 Upon announcement of fixed dates for upcoming

audits, MEDCERT shall not assume any legal responsibility to comply with these fixed dates as is applicable for the Principal.

3.15 在公布预计审核的固定日期后，MEDCERT 不应承担遵守这些固定日期的法律责任，同样适用于委托方

4. Scope of Order

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4.1 The type and scope of the services to be rendered by MEDCERT shall be clearly specified in writing by the Principal at the time of order placing and reduced to writing in a binding manner by MEDCERT in its order confirmation. The order cannot automatically be connected to a specific assessment, inspection or certification result.

4.1 MEDCERT 所提供服务的类型和范围应在下单时由委托方以书面形式明确指定，并由 MEDCERT 在订单确认中形成具有约束力的书面文件。订单无法与具体的评估、检查或认证结果自动关联。

4.2 Extensions of or amendments to orders already completed shall also be agreed upon in writing prior to their execution. If the parties fail to come to such an agreement the Principal shall be entitled to terminate the original contractual relationship. In such cases, MEDCERT's remuneration shall be subject to the statutory provisions.

4.2 对已完成订单的延期或修订也应在达成书面一致意见后方可执行。如各方未能达成一致，委托方应有权终止原始合同关系。在这种情况下，应按照法律规定向 MEDCERT 支付补偿。

4.3 Usual assistance by parties placing orders or third parties shall be put at MEDCERT's disposal without charge and in due time without the necessity to agree upon it in writing. When providing assistance the Principal shall observe the applicable statutory and administrative regulations.

4.3 MEDCERT 可免费享受下单方或第三方适时提供的一般性协助，而无需就此拟定书面协议。在提供协助时，委托方应遵守适用的法律规定和行政法规。

4.4 Partial services rendered by MEDCERT on the basis of an order and which form an own unit and can be used by the Principal shall be accepted by the Principal and paid for aainst separate invoice.

4.4 如果 MEDCERT 按照订单提供的部分服务自成一体并可由委托方使用，则委托方应接受此部分服务并单独开立发票予以支付。

5. Order Execution Periods • Fixed Dates

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5.1 Order execution periods or fixed dates shall only be binding if they have been explicitly designated as such in writing.

5.1 只有在此类书面协议中予以明确规定，订单执行期或固定日期才具备约束力。

5.2 If fixed dates are defined between the contracting parties, the parties are obliged to promptly submit and deliver their necessary requirements to comply with the fixed date. This is particularly, but not exclusively, applicable for documents and preliminary work that the Principal is obliged to deliver to MEDCERT in order to comply with fixed dates.

5.2 如果在合同方之间规定固定日期，双方有义务及时提交及提供必要的要求，以遵守固定日期。本条规定尤其但不仅仅适用于委托方为遵守固定日期有义务向 MEDCERT 提供的文档和前期工作。

5.3 Binding fixed dates shall only apply if all duties arising from clause 3.4 have been complied with in full and in due time.

5.3 具有法律效力的固定日期仅在第 3.4 条中规定的所有义务均按时且完全履行后方适用。

5.4 Fixed dates shall be extended or postponed as appropriate, or new fixed dates shall be agreed if MEDCERT fails to render its services in due time through no fault of its own. This particularly applies if the Principal is not able to meet an obligation relating to the timely provision of documents or other preliminary work important for MEDCERT's activities. This also applies during the delay in performance of the services.

5.4 如果 MEDCERT 因非自身过错而无法按时提供服务，固定日期应适当延期或推迟，或者商定新的日期。这在委托方无法履行为 MEDCERT 及时提供对其活动有重要意义的文档或前期工作的义务时尤其适用。本条规定在服务执行延迟过程中同样适用。

6. Suspension, withdrawal, restriction and refusal to issue certificates

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6.1 MEDCERT is entitled to suspend or withdraw certificates, restrict issued certificates or refuse to issue certificates based on statutory or standard regulations or if significant requirements specified at the time of certification are no longer satisfied. A refusal refers to the refusal to issue a certificate.

6.1 如果法律规定或标准法规要求，或者不再满足认证时规定的重要要求，则 MEDCERT 有权暂停或撤销证书，限制颁发或拒绝颁发证书。拒绝是指拒绝颁发证书。

6.2 The restriction specified in Section 6.1 is related to parts of products covered by a certificate or areas and activities described in a certificate. The products covered by the restriction of certificates in accordance with the European guidelines may not be placed on the market with a CE mark.

6.2 第 6.1 节规定的限制涉及到证书涵盖之部分产品或证书中载明之区域和活动。根据欧洲指导方针，证书限制所涵盖的产品在销售时不得张贴 CE 标志。

6.3 The expiration, withdrawal, revocation, restriction and suspension of a certificate may be published.

6.3 可公布证书的期满、撤销、废除、限制和暂停事宜。

6.4 MEDCERT may reach corresponding decisions if, for instance, one of the following circumstances had already been in place at the time the certificate was issued:

6.4 如果出现在证书颁发时已经存在以下任一情况，则 MEDCERT 可作出相应决策：

- the requirements from the annexes of the applicable directives required for the issuance of certificate of the quality management system or medical device were not satisfied,
- 未满足适用指令附录中的要求，这些要求是颁发质量管理体系或医疗器械证书所必需的，
- the product or product category specified in the certificate had been incorrectly assigned to a medical device,
- 证书中为医疗器械指定的产品或产品类别错误，
- the medical device or the medical device category had been assigned to a lower class and an incorrect declaration had been issued,
- 指定的医疗器械或医疗器械类别较低且颁发的声明不正确，
- the medical device submitted for the EC type eamination or the EC design examination is different from the medical device subsequently manufactured.
- 用于 EC 型式检验或 EC 设计检验的医疗器械与后来生产的医疗器械不同。

6.5 MEDCERT may also take corresponding actions if, for instance, one of the following circumstances has occurred after the certificate has been issued:

6.5 如果在证书已颁发后发生以下任一情况，则 MEDCERT 也可采取相应行动：

- the statutory requirements for the system, medical device or medical device category approved with the certification are no longer satisfied,
- 证书批准的体系、医疗器械或医疗器械类别不再满足法定要求，
- the product or product category is not, or no longer, covered by the Medical Device Directive,
- 产品和/或产品类别不包含或不再包含在医疗器械指令范围内，
- the medical device or medical device category is assigned to a lower class,
- 为医疗器械或医疗器械类别指定了较低级别，
- the medical device or the medical device category no longer satisfies the requirements such that patients, users or third parties are exposed to significant risks, or the medical device does not satisfy the intended purpose indicated by the manufacturer and these defects cannot be removed within a prescribed and appropriate period of time,
- 医疗器械或医疗器械类别不再满足要求，以致患者、用户或第三方面临很大的风险，或者医疗器械不再满足制造商指示的预期用途且这些缺陷在规定的适当时期内无法消除，
- the Principal fails to meet deadlines for correction of major nonconformities/requirements,
- 委托方无法满足纠正重大不符合情况/要求的期限，
- the Principal does not comply with their payment requirements to MEDCERT.
- 委托方未遵守其向 MEDCERT 承诺的付款条件。

6.6 Prior to taking any decision, MEDCERT shall provide the Principal with an opportunity to present the Principal's view in a hearing, unless there is urgent reason for MEDCERT to take an immediate decision precluding such a hearing. MEDCERT shall inform the Principal of the decision and specify any required measures. MEDCERT is subject to the duty of notification and shall forward any relevant status changes to certificates, including an assessment of the risk potential of the affected product(s), to the bodies concerned. The Principal is obliged to implement the measures specified by MEDCERT and must demonstrate the implementation of the measures to MEDCERT.

6.6 在作出任何决策之前，MEDCERT 应为委托方提供机会，使其能够在意见征询会上发表自己的观点，MEDCERT 因紧急原因无法召开此类征询会即而立刻作出决策的情况除外。MEDCERT 应将决策通知委托方并指定任何必要措施。MEDCERT 有通知的义务，并且应将证书的任何相关状态变化（包括受影响产品潜在风险的评估）通知相关管理机构。委托方有义务实施由 MEDCERT 指定的措施并必须向 MEDCERT 证明实施了此类措施。

7. Warranty

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7.1 MEDCERT's liability for material defects shall - within the framework of a contract for work and services - be restricted to subsequent fulfilment. If this subsequent fulfilment does not take place or fails Principal shall be entitled to a reduction of the remuneration (diminution) or a withdrawal from the contract (withdrawal) irrespective of the right arising from Section 637 of the German Civil Code.

7.1 MEDCERT 对于实质缺陷的义务应在工作和服务合同框架范围内加以限制，并随后履行。如果随后履行未执行或失败，委托方应有权减少酬金（减薪）或撤销合同（撤销），且不受德国民法典第 637 节中权利的限制。

7.2 Claims, if any, of Principal with respect to material defects shall become statute-barred 1 year after the acceptance of MEDCERT's services by Principal unless the defect has been concealed fraudulently or intentionally caused by MEDCERT.

7.2 如果委托方就实质缺陷提出索赔，则此类索赔的时效为委托方接受 MEDCERT 服务之日起 1 年，除非是 MEDCERT 有意或采用欺骗手段隐瞒缺陷。

7.3 The statutory regulations apply in all other respects.

7.3 法律规定在所有其他方面均适用。

8. Liability

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8.1 MEDCERT shall assume unlimited liability if damages are caused as a result of intent or gross negligence. MEDCERT is also liable for the slightly negligent breach of key duties (duties whose

infringement threatens the achievement of the contractual purpose) as well as for a breach of cardinal duties (duties whose fulfilment the buyer can regularly rely upon); however, only for foreseeable damages typical for the contract in each case. MEDCERT is not liable for the slightly negligent breach of duties not mentioned above.

8.1 如果损害是由于故意或重大过失造成的，则 MEDCERT 应无条件承担责任。对于违反关键职责（其侵权行为威胁到合同目的的实现）的轻微过失以及违反主要职责（买方可以经常依赖的职责）的行为，MEDCERT 也应承担责任；然而，每种情况下只适用于合同可预见的损害类型。MEDCERT 对上述未提及的轻微过失违约不承担责任。

8.2 The limitations of liability in the above paragraph do not apply in the event of the loss of life, physical injury and damage to health, for a defect after providing a guarantee for the quality of the device and in the event of fraudulently concealed defects. Liability in accordance with the Product Liability Act remains unaffected.

8.2 上述段落中的责任限制不适用于死亡、人体伤害和危及健康的情况、在提供器械质量保证后出现的缺陷以及以欺诈手段隐瞒缺陷的情况。依照产品责任法案的责任不受影响。

8.3 If MEDCERT's liability is excluded or limited, this also applies for the personal liability of employees, representatives or agents.

8.3 如果 MEDCERT 的责任已经排除或限制，这也适用于员工、代表或代理人的个人责任。

9. Remuneration

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9.1 Unless explicitly agreed upon otherwise in writing MEDCERT's price list in its current version shall apply with respect to the invoicing of its services.

9.1 除非另外明确达成一致书面意见，否则在对 MEDCERT 服务开立发票时以 MEDCERT 当前版本的价格单为准。

9.2 As far as "fixed prices" have been agreed upon explicitly in writing such prices shall apply irrespective of the time of service rendering. The Principal shall bear responsibility for any additional expenses that arise due to activities having to be repeated or postponed as a result of delayed, incorrect or incomplete information, or non-compliant duties to cooperate. MEDCERT is also entitled to invoice for these additional expenses if a fixed price has been agreed.

9.2 只要已经就“固定价格”明确达成一致书面意见，则无论何时提供服务，均应以此价格为准。委托方应对因延迟、不正确或不完整信息或不符合规定的职责合作导致活动重复或推迟所产生的任何额外费用承担责任。如果已经商定了固定日期，则 MEDCERT 也有权为这些额外费用开立发票。

9.3 The amount of statutory value added tax valid at the time being shall be identified separately in the invoice and in addition to the fees.

9.3 过程中合理产生的法定增值税应在发票中独立列出并添加到费用中。

10. Terms of Payment

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10.1 The receipt of an invoice does not automatically mean that MEDCERT has provided a bill for the entire order.

10.1 收到发票并不意味着 MEDCERT 提供了整个订单的账单。

10.2 The fee shall be due for payment no later than the date printed on the invoice.

10.2 费用应于发票上所限定日期之前支付。

10.3 In the case of orders lasting longer than one month as well as in case of completed partial services interim invoices may be issued.

10.3 如果订单持续时间超过一个月并且部分服务已完成，则可每月开一次临时发票。

10.4 MEDCERT shall be entitled to request advance payments, if necessary.

10.4 MEDCERT 有权根据需要，要求提前付款。

10.5 In the event of a default of payment by the Principal, MEDCERT shall charge default interest of 8 percentage points per annum above the base rate.

10.5 如果委托方拖欠付款，则 MEDCERT 应收取高于年基准利率 8 个百分点的违约利息。

10.6 The statutory provisions shall apply in all other respects in the event of a default of payment and in relation to an appropriate grace period.

10.6 此外，延期付款和适当的宽限期根据法律规定执行。

11. Place of Fulfilment Place of Jurisdiction Applicable Law

11. □□□・□□□□□・□□□□

11.1 If the Principal is a businessman, legal person governed by public law or a special fund under public law, the exclusive place of jurisdiction for all disputes from this contract is the place of business of MEDCERT Hamburg. The same applies if the Principal does not have a general place of jurisdiction in the Federal Republic of Germany, or if the place of residence or usual residence is unknown at the time of commencement of proceedings.

11.1 如果委托方是商人，受公法管辖的法人或公法下的专项基金，解决该合同所有争议的唯一司法管辖区是 MEDCERT 在汉堡的经营所在地。如果委托方在德意志联邦共和国没有常住地司法管辖，或者居住地或常住地在诉讼程序开始时未知，此条规定同样适用。

11.2 All disputes from this legal relationship are subject to the law of the Federal Republic of Germany. The UN Convention of Contracts for the International Sale of Goods does not apply.

11.2 该法律关系的所有争议均受德意志联邦共和国法律的约束。联合国国际货物销售合同公约不适用。

12. Severability and written form requirement

12. □□□□□□□□□□□□

12.1 The full or partial invalidity of individual provisions of this agreement between the Principal and MEDCERT or of the General Order and Payment Conditions shall not affect the validity of other provisions. The Parties are mutually obligated to replace invalid provisions with permissible provisions that fulfil the original financial intent to the closest possible extent.

12.1 委托方和 MEDCERT 之间的本协议或一般订单和付款条件中的个别条款全部或部分失效应不影响其他条款的有效性。双方均有义务以尽可能满足原有经济目的的允许条款取代无效条款。

12.2 Amendments and supplements to this contract must be made in writing to be valid. The written form requirement may only be repealed by a written agreement between the contracting parties.

12.2 本合同的修订和补充必须以书面形式制定方可生效。书面形式要求只能通过合同双方之间的书面协议方可予以废除。

Date: 2015.06.17
版本：2015 年 6 月 17 日
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