

## MCS certification process (MCS 微型发电产品认证流程)

### 适用法定范围:

TÜV Rheinland (China) Ltd.

### 适用业务范围:

P.03 Electrical  
P.04 Solar & Commercial Products

### 适用过程范围:

6.3 Service Delivery : 6.3.3 Certification

### 1. 目的

本作业指导书概述了 TÜV 莱茵实施 MCS 认证方案的认证流程。有关 MCS 产品认证的更多信息, 请访问 MCS 网站 [www.mcscertified.com](http://www.mcscertified.com)。MCS 适用于利用可再生能源发电和供热的低碳产品, 目的是通过认证使人们对低碳能源技术充满信心, 认证结果的目标市场为英国。

莱茵检测认证服务 (中国) 有限公司实施 MCS 产品认证方案的认证活动, 除需满足 MCS 认证方案的要求外, 须遵守以下法律法规 (包括但不限于) :

- 《中华人民共和国认证认可条例》
- 《认证机构管理办法》
- 《认证证书和认证标志管理办法》

本作业指导书规定了 MCS 产品认证所需的步骤, 这些步骤是在全球认证流程文件 MS-0020192 中定义的基础上进一步补充的。

### 2. 术语定义和缩写

术语/缩写	描述
MCS	MCS 微型发电产品认证方案
TR China	莱茵检测认证服务 (中国) 有限公司, 由 UKAS 或等同的机构 (即国际认可论坛 (IAF) 多边认可安排 (MLA) 的成员) 根据 ISO/ IEC 17065 合格评定认可的认证机构, 并根据 MCS 认证方案的要求对微型发电产品进行评审。
申请人	向认证机构申请 MCS 微型发电产品认证的法律实体。
子许可协议	认证机构向产品被许可人提供子许可协议。
MCS 产品认证证书持有者	该定义也适用于希望获得 MCS 产品认证的申请人。负责认证及其维护的 MCS 产品证书中指定或包含的法律实体。
已认证的 MCS 产品	已与获得许可的 MCS 认证机构成功完成 MCS 批准过程的产品。
生产方联络人	每个生产基地的指定人员, 其职责和权限包括确保建立、实施和维护质量管理体系所需的流程。

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被提名人	MCS 产品证书持有者指定的个人, MCS 产品证书持有者和认证机构之间的主要联系人。
ComPASS	莱茵 TÜV 集团内的端到端业务流程管理系统。本文件中的 <a href="#">ComPASS</a> 指 MS-0020192 中的 SPM。
MCS 010	由 MCS 标准组织制定的标准。MCS 010 产品认证方案要求: 通用工厂生产控制和产品质量要求
MCS 011	由 MCS 标准组织制定的标准。MCS 011 产品认证所要求的试验数据的采信原则
FPC	工厂生产控制 (FPC) 用于确保已认证的 MCS 产品符合并持续符合相应的标准。

### **3. 适用范围**

本作业指导书适用于 TR China 所有员工以及代表 TR China 执行与 MCS 产品认证相关活动的关联公司员工, 是 TR China 实施 MCS 产品认证方案的通用流程。MCS 产品认证方案属于 ISO/IEC 17067 中定义的类型 5 方案。其具体认证模式包括型式试验、初始工厂检查和后续监督。

MCS 产品认证方案包括以下产品及相应的标准和工具:

产品	依据	描述
定制的光伏建筑一体化产品	MCS 017	定制建筑一体化光伏标准
生物质系统	MCS 008	产品认证方案要求: 生物质
	MGD 006	敲击活动指导
热泵	MCS 007	热泵标准
	MCS 026	SCOP 和 SSHEE 计算器
	MCS 027	SPER 和 SSHEE 计算器
	MCS 028	DHW 计算器
微型热电联产成套设备或附加设备	MCS 014	产品认证方案要求: 热能主导型微型热电联产成套设备或附加设备
	MCS 015	产品认证方案要求: 电力主导的微型热电联产成套设备或附加设备
		微型热电联产附加计算器
		附加 mCHP 软件包测试方法
小型和微型风力涡轮机	MCS 006	小型风力涡轮机标准
		可再生英国小型风力涡轮机标准

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		指导说明--关于潜在新型风力涡轮机设计认证的要求
		技术说明: 关于小型风力涡轮机系统中逆变器变更的指南
太阳能光伏组件	MCS 005	太阳能光伏组件标准
太阳能集热器	MCS 004	太阳能集热器标准
太阳能安装套件	MCS 012	产品认证方案要求: 太阳能安装套件

\*MCS 的范围及其相应标准可能会更新, 最新版本可在 [MCS 网站](#) 上查阅。

\* TR China 对 MCS 产品认证活动的实施基于 MCS 公司授权, 授权范围见 [MCS 网站](#)。

### **4. 工作步骤**

下表列出了相应产品在 MCS 产品认证活动中使用的相应认证流程文件模板。

产品	测试报告模板	工厂检查计划模板	FPC 检查模板	认证检查表
定制的光伏建筑一体化产品	TRF-04128	附录 3	TRF-03438	附录 4
生物质系统				
热泵	TRF-03742	附录 3	TRF-03741	附录 4
微型热电联产成套设备或附加设备				
小型和微型风力涡轮机	TRF-03739	附录 3	TRF-03743	附录 4
太阳能光伏组件	TRF-03757	附录 3	TRF-03438	附录 4
太阳能集热器	TRF-04120	附录 3	TRF-04121	附录 4
太阳能安装套件	TRF-03733	附录 3	TRF-03732	附录 4

#### **4.1 申请 (200-300)**

##### **4.1.1 接收客户问询 (步骤 200)**

销售部收到申请人 (制造商、授权代表) 关于产品合格评定的其可能带来结果为签发证书的问询。销售部门需要从客户那里获取产品信息、文件、样品和/或技术结构文件, 因为专家需要确定产品是否符合 MCS 产品认证申请和认证的相关要求。

销售部向客户发送获得该证书所需的所有信息, 并提供相应的申请表。

各销售办公室使用的不同申请表格式均可接受。但申请表应至少包含下列中英文内容:

- 申请人信息: 申请人公司名称、地址 (与营业执照一致)。
- 证书持有人信息: 证书持有人公司名称、地址 (与营业执照一致)。
- 工厂信息: 工厂名称、地址 (与营业执照一致)。
- 发票信息 (与营业执照一致)。

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- 产品名称、型号、预期用途。
- 服务类型, 标准。
- 用户手册。

### **4.1.2 核对问询 (步骤 300)**

需要核对以下信息:

- 确保产品被包含在 MCS 的产品认证范围内;
- 确保 TR China 已获得 MCS 的授权;
- 核实客户未在“严重违法失信单位”名单中 [国家企业信用信息公示系统](#)
- 客户申请认证的标准和/或其他规范性文件。
- 客户的基本特征, 包括名称、实际地址和任何相关法律义务。
- 有关生产工厂的信息。
- 这些文件清晰易懂地说明了技术方面的问题。

所有与提供认证服务相关的项目信息都必须上传到 Compass。

### **4.2 申请评审 (400-1000)**

申请人提交合格评定申请及必要的信息、数据和文件后, 认证机构需要确保

- 提供的信息充足。
- 确认认证的范围, 包括产品、标准、法规等。
- 具备开展所有合格评定活动所需的能力。

**任何与客户的理解分歧都应在这一步骤得到解决, 以避免返工, 最坏情况下会导致合同取消。**

#### **4.2.1 确定认证范围 (步骤 400)**

应确保申请人提供的信息完整且足以确定 MCS 产品认证的适用认证要求。这也包括规范性文件、流程、可用资源以及执行所有认证活动所需的能力和资质。接收申请人关于 MCS 产品认证询问的部门 (销售、审核员或专家) 应明确澄清所需的产品信息, 以确定认证范围。需进行初步检查, 以验证所描述的产品是否包含在 TR China 被授权实施产品认证的范围内。

#### **4.2.2 标准产品 (步骤 500)**

无特殊要求, 应遵循 MCS 产品认证对产品的分类。

#### **4.2.3 打开新项目或修改现有项目 (步骤 600)**

为执行申请评审和准备报价工作, 将在 ComPASS 中打开一个新的申请评审, 并上传收到的相关文件。任务将发送给申请评审人员以检查提交的信息。

#### **4.2.4 检查提交的信息 (步骤 700)**

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需要确保客户提供的信息是完整的，并足以确定 MCS 产品认证的适用认证要求和认证流程。信息包括规范性流程、文件、可用于执行所有认证活动的能力和资质。复核人员或认证决定人员应检查客户提交的信息，具体包括以下内容：

- 申请是用于新的认证还是修改（检查是否存在相关历史记录）。
- 明确界定产品及其预期用途。
- 清晰识别产品的技术特性。
- 型号系列中不同型号之间的差异。
- 适用于产品的认证要求（规范性文件、标准）。
- 现有可接受的测试报告（见 MCS 011）。
- 进一步的资源来进行必要的测试的需求（包括检查能力）。
- 产品在 TR China 被授权实施产品认证的范围内。

申请评审人员应决定是否让其他复核人员、认证决定人员或技术能力中心的人员参与，并通过 ComPASS 触发其参与。

**注：还需检查客户在申请中提供的数据和信息在技术上是否符合标准定义和规范，如产品名称、预期用途和/或分类、取决于其范围的标准参考等。**

### **4.2.5 接受 (步骤 800)**

如果认证范围未被批准，则需要重新启动包含步骤 100 的申请过程，或者拒绝认证。在这两种情况下，在重新发起申请并且新认证文件的认证范围获得批准后，还需要在 ComPASS 中调整状态。

### **4.2.6 发起报价单并签署报价单 (步骤 900)**

向客户提交详细报价，包括与认证相关的所有信息和活动。指定的销售人员应向申请人提供一份报价单，其中包括与预期认证有关的所有相关信息以及评价阶段所涉及的使用方。在 ComPASS 中输入相关信息。

- 应与申请者签订子许可协议。（见附件 1）
- 应与申请者签订通用协议。

**注：证书持有人（包括共同证书持有人）与 TR China 之间应签订通用协议。通用协议的模板见 [TÜV Rheinland\(CN\) 主页](#)。**

### **4.2.7 建立订单 (步骤 1000)**

当客户签署并返回报价，且客户同意报价内容及所有相关信息后，指定人员应在 ComPASS 中建立订单。

## **4.3 评价 (步骤 1100-1600)**

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评价阶段始终基于评价计划。评价计划依据认证方案中对产品的要求制定。此评价计划至少包含以下内容：需要进行认证的产品、规定产品要求的标准、法规及其他规范性文件、用于评价生产过程的方法和程序。评价计划还包括具体任务的时间安排。相应的评价任务包括设计和文档审查、抽样、测试、检查和审核等活动。如果评价计划与客户签署的合同之间存在任何差异，则应启动新的申请评审和报价。如果评价过程中涉及的相关方发生变更（与合同相比），则在评价开始前应通知申请人并征得其批准。

**注：只有在报价中明确包含以上提到的内容，报价才可以被视为评价计划。**

### **4.3.1 检测 (步骤 1100)**

根据 MCS 认证方案的要求，将制定评价活动的评价计划。此评价计划规定了用于特定任务的评价方法和程序、人员及其他资源，以及时间安排。如果评价计划中涉及的评估方（如分包方）与合同相比发生变更，则必须通知申请人，并告知其有权拒绝或批准变更。检测或监督等作为认证一部分的特定订单类型也将录入 ComPASS 系统中。

客户需按照报价（评价计划）的规定，为检测实验室提供必要的样品和文件。

检测实验室根据适用标准的基本健康和安全要求，对样品（包括其附属配件、标识标签、产品随附文件（如用户手册））进行必要的测试。

检测结果将记录在测试报告中，检测报告包含对相关要求的评价。检测报告和检测文件由检测实验室根据 ISO/IEC 17025 的要求完成并出具报告。检测实验室将文件上传至 ComPASS 系统。

MCS 产品认证的测试接受准则应遵循 [MCS 011](#)。

对于不同的 MCS 产品，采用不同的 MCS 标准，详见本文件条款 3 中的表格。

### **4.3.2 工厂检查 (步骤 1200) 。**

工厂检查（工厂生产控制 FPC）应遵循 MCS 010。

所有评审应以一个启动会议开始，该会议旨在回顾评审要求、识别任何健康与安全问题并确定所需的设备。评审人员应按要求检查 FPC（工厂生产控制）流程的所有方面。任何被发现不符合要求的事项将被记录为不符合项报告。不符合项报告以及拟定的纠正措施详情（必要时包括客观证据）应在访问日期起 45 天内提交以供复查。

每种技术类别的 MCS 要求可能包含额外的 FPC 要求，但作为最低要求，应评审 MCS 011 表 1 中详细列出的要求，以确认其已在每个相关现场实施并正常运行。相关现场应由认证机构确定。

在评审或监督访问结束时，应召开总结会议，以确认评估范围并识别任何不符合项。在初次评审后，评审员会提出建议，要么在纠正不符合项（必须在 45 天内完成）的前提下，确认满足 FPC 要求；或者建议进行全面或部分重新评估。

### **4.3.3 不符合项? (步骤 1300)**

需要确定被测试产品是否符合要求，或者是否存在任何不符合项。当在产品测试和/或工厂检查中发现偏差时，制造商将收到一份详细的偏差报告，并需要在截止日期之前纠正这些偏差。

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### **4.3.4 不符合项确凿? (步骤 1400)**

当通过监督或其他方式证实与认证要求的不符合项时, 认证机构应考虑并决定适当的措施。根据 ISO/IEC 17065:2012/条款 7.11.1, 适当的措施可以包括以下内容:

- a) 按认证机构规定的条件继续认证 (例如, 增加监督频次) ;
- b) 缩小认证范围, 移除不合规的产品变型;
- c) 暂停认证, 等待客户采取补救措施;
- d) 撤销认证。

### **4.3.5 向申请人/证书持有者提交不符合项结果 (步骤 1500)**

不符合项会告知客户, 客户需要表示是否愿意继续认证程序。如果客户表示愿意继续执行认证程序, 则会提供一份评估报告, 其中包含验证纠正措施所需的额外评估任务。在提交新的评估计划之前, 必须核实是否需要执行第 900 步 (出具报价单并签署报价单)。

### **4.3.6 验证纠正措施计划 (步骤 1600)**

应验证客户是否根据其纠正措施计划在规定的时间内采取了纠正行动和措施以解决所有不符合项。一个经过修改的新样品以及说明如何处理不符合项的描述可以被视为纠正措施计划。验证可能会引发需要执行步骤 1100 (评价) 和/或步骤 1200 (工厂检查) 的需求。根据所需的纠正措施, 评价需彻底进行, 或者仅针对导致偏差报告的部分进行。客户将被及时告知验证结果。

## **4.4 复核 (1700-1900)**

### **4.4.1 确定符合性证据 (步骤 1700)**

认证机构应指定至少一人对与评价相关的所有信息和结果进行复核。复核应由公正且未参与评价过程的人员实施。

复核应包括以下内容的核查: 验证认证方案和标准的范围适用于待认证的产品; 测试实验室的能力 (参考其认可范围); 测试文档的适用性和充分性; 工厂检查报告的适用性和充分性。

MS-0049049 附件 4 认证检查表是一份详细的计划和指南, 用于执行复核及记录其结果。符合要求的确认将记录在 ComPASS 系统中, 同时也需上传所有相关的文件。

### **4.4.2 是否推荐认证? (第 1800 步)**

复核人员在复核与评价有关的所有信息、文件和结果后, 应决定是否推荐认证。如果产品和评价文件符合要求, 则复核人员推荐认证。如果不符合以下要求, 推荐拒绝认证可能会触发步骤 1300 (不符合项) 或根据步骤 1100 和/或 1200 进行新的或额外的评价。

### **4.4.3 推荐认证 (第 1900 步)**

根据复核做出的认证决定推荐应记录在认证检查表中。认证推荐将输入 ComPASS。

## **4.5 认证决定 (2000-2200 年)**

### **4.5.1 决定认证 (步骤 2000)**

## ***MCS certification process (MCS 微型发电产品认证流程)***

一旦复核人员在 ComPASS 和 SAP CORE 中上传并发布了文档和认证推荐，认证决定人员将在 ComPASS 中收到一项任务。如果认证被认证决定人员授予，他/她将在 SAP CORE 中将状态切换为状态 14。

在必要情况下，他/她可以要求复核人员检查证书内容的技术正确性。

最后，认证决定人员应确保所有认证方案的要求均已得到遵守。SAP CORE 中的所有相关信息随后将被传输至 CERTIPEDIA。MS-0049049 附件 4 认证检查表是进行认证决定和记录相关内容的详细计划和指南。认证决定将被记录在 ComPASS 中，同时需上传任何其他相关文件，特别是已完成的认证检查表。

**注意：做出认证决定的人员必须不同于参与评价的人员。然而，复核和认证决定可以由同一人或同一组人员同时完成。**

### **4.5.2 授予认证? (步骤 2100)**

如果已获得认证，则继续颁发证书（步骤 2200）。相反，如果无法颁发证书，则根据拒绝的原因，要么向客户提供一份偏差报告，要么分别重复步骤 1100（评价）和步骤 1200（工厂检查）。根据客户的答复，应采用以下选项：

- 选项 1：如果客户决定继续认证，流程将回到测试（步骤 1100）；
- 选项 2：如果客户决定不再继续认证流程，则关闭项目并开具发票。

### **4.5.3 签发证书和所需信息 (步骤 2200)**

在审核结果为正面的情况下，认证将被授予。客户将获得 CH Mark 证书。

证书应包含以下信息：

- 签发 MCS 证书的认证机构名称和地址；
- 持证人（许可证持有人）的名称和地址；
- 制造地点的名称和地址（可选）；
- 证书编号；
- 测试报告编号；
- MCS 证书的签发日期和有效期（MCS 证书有效期为 5 年）；
- 型号名称；生产批次的识别；
- 关于产品的技术信息，以便清楚地将产品与证书对应，例如：防护等级、电压、功率、尺寸等；
- 测试规范以及签发年份；
- 声明证书持有人有权在描述的产品上使用 MCS 标识，并附有 MCS 标识的图示；
- 认证决定人员的姓名；

证书可能包含一页或多页：

如果获得认证的产品在多个生产地点生产，则应列出所有生产地点。如果产品有多种变型（设计相同，但在不影响产品安全的情况下进行了一些修改），这些变型可以在同一张证书上进行组合。如果“产品描述”字段中

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空间不足，则可以在相同证书编号下添加一张补充证书页。重要的是，将所有产品变型结合在一个测试报告中，且统一提供一个测试报告编号。

通常，MCS 证书将发给客户，但不包含结构性数据表。证书的附信不应包含测试结论。结构性数据表是测试档案的一部分，但不是测试报告的必需内容，因此仅在客户特别要求的情况下提供。

如果认证未获批准，则应通过发布相关的否定性报告通知客户（ISO/IEC 17065:2012 / 第 7.6.6 条）。

在进行修正并做出正面的认证决定后，认证人员将在 CORE 中切换状态。所有相关信息将从 CORE 传输到 CERTIPEDIA 数据库。认证人员打印证书，并按要求签署（ISO/IEC 17065:2012 / 第 7.7 条）。

TR China 应在规定的表格（见附件 2）中向 MCS 提交 MCS 证书的信息。

### **4.6 监督 (2300-2900)**

监督活动包括对生产过程（FPC）的评估和/或对管理体系的审核。监督活动的重点是检查生产的产品在初次认证后是否继续满足规定的要求。负责的检查员和/或测试工程师通过采取纠正措施，验证客户已解决不符合项。

#### **4.6.1 测试、检查和审核 (步骤 2300)**

必要时，通过监督评审访问和令人满意地完成商定的产品审核测试或产品评价，维持和保持 MCS 认证的有效性。监督评审按 MCS 010 进行，以确认获得 MCS 认证的产品的 FPC 系统继续符合要求：

在提出不符合项的情况下，应在 30 天内提供关闭这些不符合项的证据。

当出现重大不符合项时，应在 12 周内进行一次重新评估（在正常评估频率之外），以检查纠正措施。

如果重大不符合项未得到充分纠正，认证机构可能会暂停相关认证；

在某些情况下，认证机构可自行决定在正常评审频率之外进行额外评价。

#### **4.6.2 不符合项? (步骤 2400)**

需要确定是否在监督活动中存在不符合项。如果没有不符合项，则可以继续进行步骤 2900。

#### **4.6.3 经证实的不符合项? (步骤 2500)**

当通过监督或其他方式确认存在与认证要求不符的不符合项时，认证机构应考虑并决定适当的措施。根据 ISO/IEC 17065:2012 / 第 7.11.1 条，以下措施可被视为适当：

- a) 在由认证机构规定的条件下继续进行认证（例如增加监督频率）；
- b) 缩小认证范围，移除不符合要求的产品变型；
- c) 暂停认证，等待客户采取纠正措施；
- d) 撤销认证

#### **4.6.4 向证书持有者提交不符合项 (步骤 2600)**

不符合项以及纠正措施的时间期限将通知客户。如果客户表示希望继续认证流程，他应提供与规定期限相关的纠正措施计划。

#### **4.6.5 核实纠正行动计划 (步骤 2700)**

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需要验证客户是否根据其纠正措施计划在规定的时间期限内采取了纠正行动和措施以解决不符合项。客户将收到相应的监督报告。

### **4.6.6 接受纠正措施? (步骤 2800)**

如果客户返回了详细的纠正措施计划且该计划满足所有认证要求，则认证将维持。在任何未满足认证要求的情况下，流程将回到评价阶段 (步骤 1100)。

### **4.6.7 认证/保持认证 (步骤 2900)**

在正面审核结果的情况下，证书的持续有效性得到确认。

在规定的有效期结束时，证书自动失效。在这种情况下，无需额外通知客户。

如果客户希望更新证书，通常可在到期前 6 个月开始提交申请。流程与新申请相同，更新后的证书应在 SAP CORE 中登记为原始证书的重新颁发，即作为现有证书编号（即 SAP CORE 编号 MR xxxxxxxx 0002、MR xxxxxxxx 0003.....）的附加“页”，其中应包含完整的最新信息。

## **4.7 影响认证的变化**

作为一般程序，任何变更的批准将通过签发原证书的修订版来确认，修订版作为现有许可证号的附加“页”（即 SAP CORE 编号 MR xxxxxxxx 0002、MR xxxxxxxx 0003.....），其中应包含前一证书页的完整和更新信息。在 4.7.1、4.8.1 或 4.8.2 中的情况下，修改后的有效期将与原始证书 (0001 张) 的有效期相同。

对于 4.7.2 中的情况，由于重新进行了合格评定，有效期被定为另一个完整期限。

更改的细节应在证书上作为附加信息标明，照片应更新（如适用），并应添加任何附加评估测试报告的参考信息。

### **4.7.1 认证产品的变更**

制造商应将对批准型号的任何修改通知认证机构，这些修改可能会影响产品与现行相应标准的基本要求或证书的有效条件的一致性，特别是在生产过程、原材料或认证产品的组件发生变化的情况下。

此类修改需要认证机构的额外批准，申请人应详细描述所有修改，并按要求提交证明文件。

修改后的产品与原认证产品之间的差异应重新评价，评价过程应遵循与新申请相同的步骤，并适当考虑所有现有的合格评定结果。

### **4.7.2 认证要求的变更**

TR China 应随时向自身及其客户通报标准化方面的任何变化和公认的技术水平。

客户应直接或通过 TÜV Rheinland 办事处获知这些变更。

客户提出申请后，如果在申请评审期间确定需要进一步评估（样品检查、测试、文件评审等），TR China 应相应通知客户。原认证产品将被重新评估，评估过程与新申请步骤相同，并适当考虑所有现有的合格评定结果。

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如果客户不申请对产品进行重新评估，则在 TR China 规定的过渡期结束后，认证可能会被取消，记录也应相应更新。

### **4.8 扩大或缩小认证范围**

"认证范围"可指列出的型号/类型、预期用途、列出的额定值（电源电压、频率等）等。

将根据 4.7 的规定确认对变更的批准。

#### **4.8.1 缩小认证范围**

如果申请人申请缩小认证范围（如取消型号），则要重新评估认证产品缩小后的范围与原范围之间的差异，并按照新申请的相同步骤进行，同时适当考虑所有现有的合格评定结果。

#### **4.8.2 扩大认证范围**

如果申请人申请扩大认证范围（如增加型号、替代比率），则要重新评估认证产品扩大范围与原有范围之间的差异，并按照新申请的相同步骤进行，同时适当考虑所有现有的合格评定结果。

### **4.9 认证的终止、暂停和撤销**

在协调相关业务领域后，认证机构、标识监督团队或商业订单处理团队可基于以下原因，决定是否需要对 MCS 产品认证进行终止、暂停或撤销：

- 客户或其制造工厂被列入“严重违法失信单位”名单中 [国家企业信用信息公示系统](#)
- 测试要求发生变更；
- 测试中发现不符合项，或未报告产品或质量管理体系的相关变更；
- 在后续检查、样品检验或审核中发现不符合项；
- 拒绝进入生产场所、存储设施或需审核的区域；
- 滥用认证，例如错误引用认证内容，或误导性使用证书和测试标志；
- 拒绝提供访问相关记录的权限；
- 未支付相关费用；
- 未履行向认证机构报告需报告事件的义务。

如果需要根据上述任一原因采取行动，根据职责分工，标识监督团队、商业订单处理团队或认证机构将启动相关问题处理流程，通常会邀请相关认证决定人员参与。将应在合理时间内努力澄清情况。如果问题无法解决，且前述问题仍然存在致使必须终止、暂停或撤销 MCS 产品认证证书，认证机构、标识监督团队或商业订单处理团队将终止、暂停或撤销 MCS 产品认证证书，并在核心系统（CORE 系统）中发起相关证书的撤销或取消程序。如有必要，还会通知相关主管部门或其他认证机构。

#### **4.9.1 终止认证**

应客户要求，证书可在有效期结束前终止。认证机构应要求证书持有者（制造商）提交终止证书的书面申请，并相应更新记录。

注：客户无权要求退还已支付的产品认证注册费。

## ***MCS certification process (MCS 微型发电产品认证流程)***

### **4.9.2 认证的暂停和撤销**

如果发现认证产品不符合 MCS 认证相关要求中规定的基本要求, 或在 4.7.2 中描述的条件下, 认证证书将被撤销。

如果市场监督管理总局或方案所有者发现认证产品不符合相关 MCS 认证规定的基本要求, 可指示认证机构撤销相关证书。

在对不符合项调查结果进行调查并得出结论之前, 认证机构可暂停认证, 并通知证书持有者, 同时应相应更新记录。

如果调查表明无法确认不符合项, 或证书持有者已采取适当的补救措施, 则可恢复被暂停证书的有效性, 并应相应更新记录。

如果调查表明不符合项可以确认, 而证书持有者没有在规定的时间内采取适当的补救措施, 则应撤销被暂停的证书, 并相应地更新记录。

### **4.10 产品认证文件的保留期限**

所有与认证相关的书面记录或电子存储信息必须至少保留 2 年, 具体起始时间为证书失效、撤销或被宣布无效之后。

### **4.11 MCS 认证标识的使用**

MCS 认证标识的使用参见 MCS 网站 [MCS Certification Mark - MCS](#)



\*上述 MCS 标识样式仅供示意之用, 未经产品认证不得使用。

### **4.12 认证费用**

MCS 认证始终需要支付证书费用。年度证书费用的金额以增量单元定义。证书费用由证书持有人在每年年初支付。通常, 证书费用与在证书下生产或销售的获批类型产品数量无关。

### **4.13 认证的有效期及过渡期**

TÜV 莱茵 MCS 产品认证证书的有效期为 5 年。

MCS 认证方案及其标准变更所引起的证书有效性的变化的过渡期以 MCS 官方通知为准, TR China 有义务通知其客户相关信息。

## **5. 岗位和职责**

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流程角色	责任
认证决定人员	请参阅 SOP MS-0020192 "认证决定人员"。
复核人员	请参阅 SOP MS-0020192 "复核人员"。
评审人员	请参阅 SOP MS-0020192 "评审人员"。
申请评审人员	请参阅 SOP MS-0020192 "申请评审人员"。
销售人员	请参阅 SOP MS-0020192 "销售人员"。

### **6. 规范**

N/A

### **7. 附件**

*Attachment 1 of MS-0049049 Sub-licence agreement.docx*

*Attachment 2 of MS-0049049 MCS\_Products\_Upload\_Template.xls*

*Attachment 3 of MS-0049049 Factory Inspection Plan Template.docx*

*Attachment 4 of MS-0049049 Certification Checklist.pdf*

### **8. 相关文件**

*MS-0020192 - Global Product Certification Process*

### **9. 外部参考文件**

*MCS 010*

*MCS 011*

*MCS 005*

*MCS Certification Mark*

*MCS 004*

*MCS 008*

*MCS 006*

*MCS 017*

*MCS 007*

*MCS 014*

*MCS 015*

*MCS 012*

## ***MCS certification process (MCS 微型发电产品认证流程)***

**Legal Scope:**

TÜV Rheinland (China) Ltd.

**Business Scope:**

P.03 Electrical  
P.04 Solar & Commercial Products

**Process Scope:**

6.3 Service Delivery : 6.3.3 Certification

### **1. Objectives**

This Work Instruction outlines the certification process implemented by TÜV Rheinland for the MCS certification scheme. For more information on MCS product certification, please visit the MCS website at [www.mcs-certified.com](http://www.mcs-certified.com).

MCS applies to low-carbon products used for power generation and heating via renewable energy sources, with the aim of building public confidence in low-carbon energy technologies through certification. The target market for the certification results is the United Kingdom.

The certification activities conducted by TÜV Rheinland (China) Ltd. under the MCS product certification scheme must comply not only with the requirements of the MCS certification scheme but also with the following laws and regulations (including but not limited to):

- Regulations of the People's Republic of China on Certification and Accreditation
- Measures for the Administration of Certification Bodies
- Measures for the Administration of Certificates and Marks

This Work Instruction specifies the steps required for MCS product certification, which are further supplemented based on the global certification process document MS-0020192.

### **2. Terms and Abbreviations**

Terms/Abbreviations	Description
MCS	Microgeneration Certification Scheme.
TRCH	TÜV Rheinland (China) Ltd. A Certification Body that is accredited in accordance with ISO/ IEC 17065 conformity assessment by UKAS or an equivalent (ie. a member of the International Accreditation Forum (IAF) Multilateral Recognition Arrangement (MLA) and undertakes the assessment of microgeneration products against the requirements of MCS certification scheme.
Applicant	The legal entity applying to the Certification Body for the MCS certification of microgeneration product(s).
Sub-liscence agreement	Certification bodies provide a sub-license agreement to product licensees.
MCS Product Certificate Holder	This definition also applies to applicants who wish to have products certified under MCS. The legal entity named or to be included in the MCS product certificate that has responsibility for certification and its maintenance.

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MCS Certified Product(s)	A product in relation to which the MCS Approval process with a licensed MCS Certification Body has been completed successfully.
Manufacturing Contact	The named individual at each manufacturing site with responsibilities and authority that includes ensuring that processes needed for the quality management system are established, implemented and maintained.
Nominee	A named individual of the MCS Product Certificate Holder who is the primary contact between the MCS Product Certificate Holder and the Certification Body.
ComPASS	An end-to-end business process management system within TÜV Rheinland group. <a href="#">ComPASS</a> in this document refers to the SPM in MS-0020192.
MCS 010	A standard established by MCS standard organisation. MCS 010 Product Certification Scheme Requirements: Generic Factory Production Control and Product Quality Requirements
MCS 011	A standard established by MCS standard organisation. MCS 011 Product Certification Scheme Requirements: Acceptance Criteria for Testing Required for Product Certification
FPC	Factory Production Control (FPC) is used to ensure that MCS Certificated Products meet and continue to meet the appropriate standards.

### **3. Scope of Application**

This Work Instruction applies to all TR China employees, as well as employees of affiliated companies acting on behalf of TR China to perform activities related to MCS product certification. It serves as the general process for the implementation of the MCS product certification scheme by TR China. The MCS product certification scheme is classified as a Type 5 scheme as defined in ISO/IEC 17067. Its specific certification model includes type testing, initial factory inspection, and subsequent surveillance.

The MCS certification scheme includes products and corresponding standards and tools as follows:

Products	Reference	Description
Bespoke Building Integrated Photovoltaic Products	MCS 017	The Bespoke Building Integrated Photovoltaic Standard
Biomass Systems	MCS 008	Product Certification Scheme Requirements: Biomass
	MGD 006	Percussive Events Guidance
Heat Pumps	MCS 007	The Heat Pump Standard
	MCS 026	SCOP and SSHEE Calculator
	MCS 027	SPER and SSHEE Calculator
	MCS 028	DHW Calculator
Micro CHP	MCS 014	Product Certification Scheme Requirements: Heat-led micro-cogeneration packages or add-on units
	MCS 015	Product certification scheme requirements: Electricity-led micro-cogeneration packages or add-on units
		Micro-cogeneration add on calculator

## ***MCS certification process (MCS 微型发电产品认证流程)***

		Add-On mCHP package test methodology
Small and Micro Wind Turbines	MCS 006	The Small Wind Turbine Standard
		Renewable UK small wind turbine Standard
		Guidance Note – requests regarding certification of potentially novel wind turbine designs
		Technical Note: guidance regarding inverter changes in small wind turbine systems
Solar PV	MCS 005	The Solar PV Standard
Solar Thermal	MCS 004	The Solar Heating Standard
Solar Mounting Kits	MCS 012	Product Certification Scheme Requirements: Solar Mounting Kits

\*The scope of MCS and its corresponding standards may be updated, the latest version can be found on the [MCS website](#).

\*The implementation of MCS product certification activities by TR China is based on the authorization granted by MCS company, with the scope of authorization shown on the [MCS website](#).

### **4. Activities**

The following table shows the corresponding certification process document template used by the corresponding product during the MCS product certification activity.

Products	Test report template	Factory inspection plan template	FPC report template	Certification checklist
Bespoke Building Integrated Photovoltaic Products	TRF-04128	Attachement 3	TRF-03438	Attachement 4
Biomass Systems				
Heat Pumps	TRF-03742	Attachement 3	TRF-03741	Attachement 4
Micro CHP				
Small and Micro Wind Turbines	TRF-03739	Attachement 3	TRF-03743	Attachement 4
Solar PV	TRF-03757	Attachement 3	TRF-03438	Attachement 4
Solar Thermal	TRF-04120	Attachement 3	TRF-04121	Attachement 4
Solar Mounting Kits	TRF-03733	Attachement 3	TRF-03732	Attachement 4

#### **4.1 Application (200-300)**

##### **4.1.1 Receive customer inquiry (step 200)**

Sales receives inquiry from Applicant (manufacturer, authorized representative) regarding product conformity assessment that may result in issuing a certificate. Sales need to receive product information, documents, sample(s) and/or technical construction files from customer because the expert must determine whether the product complies with the relevant requirements for CH Mark application and certification.

Sales sends all information to client, which is necessary for application and provides the appropriate application form.

Various forms used by Sales offices to document the application are acceptable. However, it should at least contain the following application content in Chinese and English.

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- Applicant information: company name of applicant, address (consistent with business license).
- License holder information: company name of license holder, address (consistent with business license).
- Factory information: company name of factory, address (consistent with business license).
- Invoice information (consistent with business license).
- Product name, model/type designation, intended use.
- Services, Standard(s).
- User manual.

### **4.1.2 Check inquiry (step 300)**

The following information must be verified:

- Ensure that the product is included within the scope of MCS product certification.
- Ensure that TR China is authorized under the MCS scheme.
- Verify that the client is not listed in the "List of Entities with Serious Violations of Law or Trustworthiness" in the National Enterprise Credit Information Publicity System.
- Confirm the standards and/or other normative documents under which the client is applying for certification.
- Verify the client's basic details, including name, physical address, and any associated legal obligations.
- Gather information about the manufacturing plant.
- Ensure that the submitted documents clearly and comprehensively address technical matters.

All project related information that are relevant for providing the certification service have to be uploaded to Compass.

### **4.2 Application Review (400-1000)**

After the applicant submits the conformity assessment application along with the necessary information, data, and documents, the certification body must ensure the following:

- The submitted information is sufficient.
- The certification scope is clearly defined, including products, standards, regulations, etc.
- The certification body has the necessary capability to perform all conformity assessment activities.

**Any misunderstandings with the client should be resolved at this stage to avoid rework, which, in the worst-case scenario, could result in contract termination.**

### **4.2.1 Determine scope of certification (step 400)**

It must be ensured that the information provided by the applicant is complete and sufficient to determine the applicable certification requirements for MCS product certification. This includes normative documents, processes, available resources, as well as the capability and qualifications required to perform all certification activities.

The department receiving the applicant's inquiries regarding MCS product certification (Sales, Auditors, or Experts) must clearly clarify the required product information to define the certification scope. A preliminary review must be conducted to verify whether the described product is within the authorized scope of TR China to conduct product certification.

### **4.2.2 Standard Product (step 500)**

Unless otherwise specified, the classification of products for MCS product certification should be followed.

### **4.2.3 Open new project or amend an existing project (step 600)**

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To carry out the application review and prepare the quotation, a new application review will be created in ComPASS, and the relevant documents received will be uploaded. The task will be assigned to the application reviewer to verify the submitted information.

### **4.2.4 Check of submitted information (step 700)**

It must be ensured that the information provided by the client is complete and sufficient to determine the applicable certification requirements and certification processes for MCS product certification. The information includes normative processes, documents, and the capability and qualifications necessary to perform all certification activities.

The reviewer or certification decision-maker should examine the information submitted by the client, specifically including the following:

- Whether the application is for new certification or a modification (check for any relevant historical records).
- Clearly define the product and its intended use.
- Accurately identify the technical characteristics of the product.
- Differences between models within a product series.
- Certification requirements applicable to the product (normative documents, standards).
- Existing acceptable test reports (refer to MCS 011).
- The need for additional resources to carry out necessary testing (including verification of capability).
- Whether the product falls within the scope of TR China's authorization to conduct product certification.

The application reviewer should decide whether to involve additional reviewers, certification decision-makers, or personnel from the Technical Competence Center, and trigger their participation through ComPASS.

***Note: It is also necessary to verify whether the data and information provided by the client in the application technically comply with the definitions and specifications outlined in the standards, such as product name, intended use and/or classification, and the standard references depending on its scope.***

### **4.2.5 Acceptance (step 800)**

If the certification scope is not approved, the application process, including Step 100, must be restarted, or the certification must be rejected. In either case, after the application is reinitiated and the certification scope of the new certification documents is approved, the status must also be updated in ComPASS.

### **4.2.6 Issue quotation & sign quote (step 900)**

Submit a detailed quotation to the client, including all information and activities related to certification. The designated sales personnel should provide the applicant with a quotation that includes all relevant information related to the intended certification and the parties involved in the evaluation stage. Enter the relevant information into ComPASS.

- A sub-licensing agreement must be signed with the applicant. (See Attachment 1)
- A general agreement must be signed with the applicant.

***Note: A general agreement must be signed between the certificate holder (including co-certificate holders) and TR China. The template for the general agreement can be found on the [TÜV Rheinland\(CN\) website](#).***

### **4.2.7 Open order (step 1000)**

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When the client signs and returns the quotation, agreeing to its content and all related information, the designated personnel should create an order in ComPASS.

### **4.3 Evaluation (step 1100-1600)**

The evaluation phase is always based on an evaluation plan. The evaluation plan is developed in accordance with the product requirements outlined in the certification scheme. This evaluation plan must include, at a minimum, the following: the product(s) to be certified, the standards, regulations, and other normative documents specifying the product requirements, and the methods and procedures for evaluating the production process. The evaluation plan also includes a timeline for specific tasks. Corresponding evaluation tasks include activities such as design and document review, sampling, testing, inspection, and audits. If there are any differences between the evaluation plan and the contract signed with the client, a new application review and quotation must be initiated. If any changes occur in the relevant parties involved in the evaluation (compared to the contract), the applicant must be informed and their approval obtained prior to starting the evaluation.

***Note: The quotation can only be considered as the evaluation plan if it explicitly includes the above-mentioned content.***

#### **4.3.1 Testing (step 1100)**

In accordance with the requirements of the MCS certification scheme, an evaluation plan will be developed for evaluation activities. This evaluation plan specifies the evaluation methods and procedures, personnel, and other resources, as well as a timeline for specific tasks. If there are changes to the assessment parties (e.g., subcontractors) involved in the evaluation plan compared to the contract, the applicant must be informed and notified of their right to reject or approve such changes.

Specific order types, such as testing or surveillance as part of the certification, will also be entered into the ComPASS system.

The client is required to provide necessary samples and documentation to the testing laboratory as stipulated in the quotation (evaluation plan).

The testing laboratory performs the required tests on the samples (including their auxiliary accessories, labeling, and accompanying product documentation such as user manuals) in accordance with the basic health and safety requirements of the applicable standards.

The test results are documented in a test report, which includes an evaluation of the relevant requirements. The test report and testing documents are completed and issued by the testing laboratory in compliance with ISO/IEC 17025 requirements. The testing laboratory uploads the documents to the ComPASS system.

The testing acceptance criteria for MCS product certification must comply with MCS 011.

Different MCS standards are applied for different MCS products. For details, refer to the table in Clause 3 of this document.

#### **4.3.2 Factory inspection (step 1200)**

Factory inspections (Factory Production Control, FPC) must follow MCS 010.

All assessments should begin with an opening meeting, which aims to review the assessment requirements, identify any health and safety issues, and determine the necessary equipment. The assessor is required to examine all aspects of the FPC processes as specified. Any identified non-conformities will be recorded in a Non-Conformity Report (NCR). The Non-Conformity Report, along with the proposed corrective actions

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(including objective evidence, if necessary), must be submitted for review within 45 days from the date of the visit.

The MCS requirements for each technical category may include additional FPC requirements. However, as a minimum, the requirements detailed in Table 1 of MCS 011 must be assessed to confirm they are implemented and functioning correctly at each relevant site. Relevant sites will be determined by the certification body.

At the end of the assessment or surveillance visit, a closing meeting must be held to confirm the scope of the assessment and to identify any non-conformities. Following the initial assessment, the assessor will make a recommendation to either confirm that the FPC requirements are met, subject to the resolution of non-conformities (which must be resolved within 45 days), or recommend a full or partial reassessment.

### **4.3.3 Non-conformities? (step 1300)**

It must be determined whether the tested product meets the requirements or if there are any non-conformities. When deviations are identified during product testing and/or factory inspection, the manufacturer will receive a detailed deviation report and will be required to correct these deviations before the specified deadline.

### **4.3.4 Substantiated Non-conformities? (step 1400)**

When non-conformities with certification requirements are substantiated through surveillance or other means, the certification body must consider and decide on appropriate actions. According to ISO/IEC 17065:2012/Clause 7.11.1, appropriate actions may include the following:

- a) Continuing certification under conditions specified by the certification body (e.g., increasing the frequency of surveillance);
- b) Reducing the scope of certification, removing non-compliant product variants;
- c) Suspending certification, pending corrective actions from the client;
- d) Withdrawing the certification.

### **4.3.5 Submit result on nonconformities to the applicant/certificate holder (step 1500)**

Non-conformities will be communicated to the client, who will need to indicate whether they wish to continue the certification process. If the client decides to proceed, an evaluation report will be provided, which includes additional evaluation tasks required to verify the corrective actions. Before submitting a new evaluation plan, it must be verified whether Step 900 (issuing and signing the quotation) needs to be carried out.

### **4.3.6 Verify the corrective action plan (step 1600)**

It must be verified whether the client has implemented corrective actions and measures within the specified timeline to address all non-conformities according to their corrective action plan. A modified new sample and a description detailing how the non-conformities have been addressed can be considered part of the corrective action plan.

Verification may trigger the need to carry out Step 1100 (Evaluation) and/or Step 1200 (Factory Inspection). Depending on the required corrective actions, the evaluation must be conducted comprehensively or only for the parts that caused the deviation report. The client will be promptly informed of the verification results.

## **4.4 Review (1700-1900)**

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### **4.4.1 Determine conformity evidence (step 1700)**

The certification body must designate at least one person to review all information and results related to the evaluation. The review must be carried out impartially by individuals who were not involved in the evaluation process.

The review must include verification of the following aspects:

- Confirmation that the certification scheme and standard apply to the product to be certified.
- The competence of the testing laboratory (referencing its accreditation scope).
- The applicability and adequacy of the testing documentation.
- The applicability and adequacy of the factory inspection report.

Attachment 4 of MS-0049049 Certification Checklist provides a detailed plan and guideline for performing reviews and recording their results. Confirmation of compliance must be recorded in the ComPASS system, and all relevant documents must also be uploaded.

### **4.4.2 Certification recommended? (step 1800)**

Following the review of all information, documents, and results related to the evaluation, the reviewer must decide whether to recommend certification or not. If the product and evaluation documents meet all requirements, certification is recommended. If the requirements are unmet, rejecting the certification may trigger Step 1300 (Non-Conformance) or require new or additional evaluations based on Step 1100 (Testing) and/or Step 1200 (Factory Inspection).

### **4.4.3 Recommend certification (step 1900)**

The recommendation for certification based on the review must be documented in the certification checklist. The certification recommendation will be entered into ComPASS.

## **4.5 Certification decision (2000-2200)**

### **4.5.1 Decide on Certification (step 2000)**

Once the reviewer has uploaded and submitted the documents and certification recommendation in ComPASS and SAP CORE, the certification decision-maker will receive a task in ComPASS. If the certification is granted, the decision-maker will change the status in SAP CORE to status 14.

If necessary, the decision-maker can request the reviewer to verify the technical accuracy of the certificate content.

Finally, the certification decision-maker must ensure that all requirements of the certification scheme have been fulfilled. All relevant information in SAP CORE will then be transferred to CERTIPEDIA. Attachment 4 of MS-0049049 Certification Checklist provides a detailed plan and guideline for making certification decisions and recording them. Certification decisions must be recorded in ComPASS, and any additional relevant documents, particularly the completed certification checklist, must also be uploaded.

***Note: The individual making the certification decision must differ from the individual(s) involved in the evaluation. However, the review and certification decision can be conducted by the same person or group of persons simultaneously.***

### **4.5.2 Certification granted? (step 2100)**

If certification is granted, proceed to issue the certificate (Step 2200). If the certificate cannot be issued, the client must be provided with either a deviation report or, depending on the reason for rejection, Steps 1100

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(Testing) and 1200 (Factory Inspection) must be repeated. Based on the client's response, one of the following options should be applied:

- **Option 1:** If the client decides to continue the certification process, the process will return to testing (Step 1100).
- **Option 2:** If the client decides not to proceed with the certification process, the project will be closed, and an invoice will be generated.

### **4.5.3 Issue certificate and any required information (step 2200)**

If the result of the review is positive, the certification will be granted, and the client will receive the CH Mark certificate.

The certificate must include the following information:

- The name and address of the certification body issuing the MCS certificate.
- The name and address of the certificate holder (licensee).
- The name and address of the manufacturing location (optional).
- Certificate number.
- Test report number.
- The issuance date and validity period of the MCS certificate (MCS certificates are valid for 5 years).
- Model name(s) and production batch identification.
- Technical information about the product to clearly match it with the certificate, such as protection rating, voltage, power, dimensions, etc.
- Testing specifications and the year of issuance.
- A declaration that the certificate holder is authorized to use the MCS mark on the described product, accompanied by an illustration of the MCS mark.
- The name of the certification decision-maker.
- The certificate may consist of one or more pages:
- If certified products are manufactured at multiple production sites, all production locations must be listed.
- If a product has multiple variants (same design with some modifications that do not affect product safety), these variants can be grouped on the same certificate.
- If the "Product Description" field does not provide enough space, a supplementary certificate page with the same certificate number may be added.

It is important to ensure that all product variants are consolidated into a single test report with one test report number.

In general, the MCS certificate will be issued to the client but will not include a structural datasheet. The accompanying letter for the certificate must not include test conclusions. The structural datasheet is part of the testing file but is not a mandatory component of the test report and is only provided upon specific client request.

If certification is not granted, the client must be notified by issuing a corresponding rejection report (ISO/IEC 17065:2012 / Clause 7.6.6).

Once corrections are made and a positive certification decision is finalized, the certification officer will change the status in CORE. All relevant information will be transferred from CORE to the CERTIPEDIA database. The certification officer will print the certificate and sign it as required (ISO/IEC 17065:2012 / Clause 7.7).

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TR China must submit information about the MCS certificate to MCS using the specified form (see Attachment 2).

### **4.6 Surveillance (2300-2900)**

Surveillance activities include the evaluation of the production process (FPC) and/or audits of the management system. The focus of surveillance activities is to verify whether the products being manufactured continue to meet the specified requirements after the initial certification. The responsible inspector and/or test engineer verifies that the client has resolved non-conformities through the implementation of corrective actions.

#### **4.6.1 Testing, Inspection, Auditing (step 2300)**

When necessary, the validity and maintenance of MCS certification are ensured through surveillance review visits and the satisfactory completion of agreed-upon product testing or evaluation. Surveillance reviews are conducted in accordance with **MCS 010** to ensure that the FPC system of certified products continues to meet requirements:

- In the event of non-conformities, evidence of their resolution must be provided within 30 days.
- For major non-conformities, a reassessment must be conducted within 12 weeks (outside the normal assessment frequency) to verify corrective actions.
- If major non-conformities are not adequately resolved, the certification body may suspend the relevant certification.
- In certain cases, the certification body may independently decide to conduct additional evaluations outside the normal review frequency.

#### **4.6.2 Non-conformities? (step 2400)**

It must be determined whether non-conformities were identified during surveillance activities. If no non-conformities are found, proceed to Step 2900.

#### **4.6.3 Substantiated Non-conformities? (step 2500)**

If non-conformities with certification requirements are confirmed through surveillance or other means, the certification body must consider and decide on the appropriate actions. According to **ISO/IEC 17065:2012, Clause 7.11.1**, the following actions may be considered appropriate:

- a) Continuing certification under conditions defined by the certification body (e.g., increased surveillance frequency);
- b) Reducing the scope of certification by removing non-compliant product variants;
- c) Suspending certification, pending corrective actions from the client;
- d) Revoking certification.

#### **4.6.4 Submit result on nonconformities to the certificate holder (step 2600)**

Non-conformities and the corrective action deadlines will be communicated to the client. If the client expresses the intent to continue the certification process, they must provide a corrective action plan within the specified timeframe.

#### **4.6.5 Verify the corrective action plan (step 2700)**

It must be verified whether the client has implemented corrective actions and measures within the specified timeframe to resolve the non-conformities. The client will receive a corresponding surveillance report.

#### **4.6.6 Ok (Corrective actions accepted)? (step 2800)**

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If the client submits a detailed corrective action plan that fulfills all certification requirements, certification will be maintained. If certification requirements are not met, the process will revert to the evaluation stage (Step 1100).

### **4.6.7 Certification / Maintain Certification (step 2900)**

If the audit results are positive, the ongoing validity of the certificate is confirmed.

At the end of the specified validity period, the certificate will expire automatically. In such cases, no additional notification needs to be sent to the client.

If the client wishes to renew the certificate, they may apply up to 6 months before its expiration date. The process will follow the same steps as a new application, and renewed certificates should be recorded in **SAP CORE** as reissuances of the original certificate. This will serve as an additional "page" of the existing certificate number (e.g., SAP CORE Number MR xxxxxxxx 0002, MR xxxxxxxx 0003...), containing complete and updated information.

### **4.7 Changes affecting the certification**

As general process any approval of changes will be confirmed by issuing a revision of the original certificate as an additional "sheet" to the existing license no. (i.e. in SAP CORE numbering MR xxxxxxxx 0002, MR xxxxxxxx 0003...) which shall contain the full and updated information of previous certificate sheet.

The revision will maintain the same validity date as the original certificate (sheet 0001) in cases in 4.7.1, 4.8.1 or 4.8.2.

For cases in 4.7.2 the validity is set at another full term due to the renewed conformity assessment.

Details of the changes shall be identified as additional information on the certificate, photos updated (if applicable) and references to any additionally evaluated test reports shall be added.

#### **4.7.1 Changes to the certified product**

Manufacturers must notify the certification body of any modifications to the approved models that may affect compliance with the fundamental requirements of the current standards or the conditions under which the certificate was granted. This applies especially to changes in production processes, raw materials, or components of the certified products.

Such modifications require additional approval from the certification body. The applicant must submit a detailed description of all modifications along with any supporting documentation as required.

The differences between the modified product and the original certified product must be reevaluated. The evaluation process must follow the same steps as a new application while appropriately considering all existing conformity assessment results.

#### **4.7.2 Changes to the certification requirements**

TR China must keep itself and its clients updated on any changes in standards or technological advancements.

Clients should be informed of such changes directly or through TÜV Rheinland offices.

If additional evaluations are determined to be necessary during the application review (e.g., sample inspections, testing, document reviews), TR China must notify the client accordingly. The originally certified product will then be reevaluated following the same steps as a new application, while appropriately considering all existing conformity assessment results.

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If the client does not apply for reevaluation of the product, certification may be canceled after the transition period specified by TR China, and records must be updated accordingly.

### **4.8 Extending or reducing scope of a certification**

“Scope of certification” may refer to the listed models / types, their intended use, listed ratings (supply voltage, frequency etc.) etc.

Approval of changes will be confirmed in accordance with 4.7.

#### **4.8.1 Reducing scope of certification**

If applicant applies to reduce the scope of certification (e.g. cancellation of models), the difference between the reduced and original scope for the certified product is re-evaluated and the process follows the same steps as a new application, taking all existing conformity assessment results into account.

#### **4.8.2 Extending scope of certification**

If applicant applies to extend the scope of certification (e.g. addition of models, alternative ratings), the difference between the extended and original scope for the certified product is re-evaluated and the process follows the same steps as a new application, taking all existing conformity assessment results into account.

### **4.9 Termination, Suspension and Withdrawal of certification**

After coordinating with relevant business areas, the certification body, mark surveillance team, or business order processing team may decide to terminate, suspend, or revoke MCS product certification for the following reasons:

- The client or its manufacturing site is included in the "List of Entities with Serious Violations of Law or Trustworthiness" as published in the National Enterprise Credit Information Publicity System.
- Changes in testing requirements.
- Discovery of non-conformities during testing or failure to report changes in certified products or the quality management system.
- Non-conformities identified during follow-up inspections, sample inspections, or audits.
- Refusal to grant access to production sites, storage facilities, or areas required for audits.
- Misuse of certification (e.g., misrepresentation of certification or misleading use of certificates and test marks).
- Refusal to provide access to relevant records.
- Non-payment of applicable fees.
- Failure to fulfill notification obligations to the certification body.

If action is required due to any of the above reasons, the mark surveillance team, business order processing team, or certification body will initiate the appropriate issue-handling process, typically involving relevant certification decision-makers. Efforts must be made to clarify the situation within a reasonable timeframe.

If the issue cannot be resolved and the identified problems persist, the certification body, mark surveillance team, or business order processing team will terminate, suspend, or revoke the MCS product certification.

The revocation or cancellation process will be initiated in the CORE system, and relevant authorities or other certification bodies will be notified if necessary.

#### **4.9.1 Termination of certification**

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On client's request the certificate may be terminated before reaching the end its validity term. The certification body shall require a written request for termination from the certificate holder (manufacturer), and records shall be updated accordingly.

*Note: The client is not entitled to receive a refund for any registration fees already paid for the certification of product.*

### **4.9.2 Suspension and Withdrawal of certification**

Certificate will be withdrawn if the certified product is found not to comply with the Essential Requirements set out in the concerned requirement of MCS certification or under the conditions described in 4.7.2.

If Market Surveillance Authority or scheme owner finds that a certified product is not in conformity with the Essential Requirements set out in the concerned MCS certification it may instruct the CAB to withdraw related certificates.

While investigating the non-conformity findings and until reaching a conclusion the CAB may suspend a certification, inform the certificate holder, and records shall be updated accordingly.

Should the investigation demonstrate that the non-conformities could not be confirmed or if the holder of the certificate has taken appropriate remedial actions, the validity of the suspended certificate may be reinstated, and records shall be updated accordingly.

Should the investigation demonstrate that the non-conformities could be confirmed and the holder of the certificate did not take appropriate remedial actions within the provided timeframe, the suspended certificate shall be withdrawn, and records shall be updated accordingly.

### **4.10 Retention Period for Product Certification Documents**

All written records or electronically stored information related to certification must be retained for a minimum of 2 years, starting from the date when the certificate becomes invalid, is revoked, or is declared void.

### **4.11 Use of the MCS Certification Mark**

The use of the MCS certification mark follows the guidelines provided on the MCS website: [MCS Certification Mark - MCS](#).



**CERTIFIED**

*\*The above MCS mark design is for illustrative purposes only and must not be used without product certification.*

### **4.12 Certification Fees**

MCS certification always requires payment of certificate fees. The amount of the annual certificate fee is defined by incremental units. Certificate fees are paid by the certificate holder at the beginning of each

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year. Typically, the certificate fee is not related to the quantity of approved products produced or sold under the certificate.

### **4.13 Certification Validity and Transition Period**

The TÜV Rheinland MCS Product Certification Certificate is valid for 5 years.

Changes to certificate validity caused by modifications to the MCS certification scheme and its standards are subject to the transition periods specified in official MCS notifications. TR China is obligated to inform its clients of this relevant information.

## **5. Roles & Responsibilities**

Process Roles	Responsibilities
Certifier	Please refer to SOP MS-0020192 "Certifier"
Reviewer	Please refer to SOP MS-0020192 "Reviewer"
Assessor	Please refer to SOP MS-0020192 "Evaluator"
Application Reviewer	Please refer to SOP MS-0020192 "Application Reviewer"
Sales	Please refer to SOP MS-0020192 "Sales"

## **6. Specifications**

N/A

## **7. Attachments**

*Attachment 1 of MS-0049049 Sub-licence agreement.docx*

*Attachment 2 of MS-0049049 MCS\_Products\_Upload\_Template.xls*

*Attachment 3 of MS-0049049 Factory Inspection Plan Template.docx*

*Attachment 4 of MS-0049049 Certification Checklist.pdf*

## **8. Related Documents**

*MS-0020192 - Global Product Certification Process*

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### **9. External Reference Documents**

*MCS 010*  
*MCS 011*  
*MCS 005*  
*MCS Certification Mark*  
*MCS 004*  
*MCS 008*  
*MCS 006*  
*MCS 017*  
*MCS 007*  
*MCS 014*  
*MCS 015*  
*MCS 012*



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微型发电产品标准：MCS 010

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MCS 产品认证方案要求：

通用工厂生产控制和产品质量要求

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本微型发电产品标准为 MCS 慈善基金会所有，位于 Suite F40, Innovation Centre, Sci - Tech  
Daresbury, Keckwick Lane, Cheshire WA4 4FS. 注册慈善机构编号 1165752

本标准已获得微型发电认证方案的标准管理小组的批准。

### 微型发电标准修订

微型发电将会通过发布修订版或修订案来修订，

具体内容将在网站 [www.mcscertified.com](http://www.mcscertified.com) 上公布

如果有影响产品或服务的批准或认证要求的技术或其他方面的变更，将会发行新版本的标准。轻微的或管理上的改变(例如更正拼写和印刷错误，更改地址和版权细节，增加澄清注释等)可以仅作为修订。

发行号将以十进制格式给出，整数部分给出发行号，小数部分给出修订的数量(例如发行号 3.2 表示该文件是第 3 版，有 2 项修订)。

本标准的使用者应确保拥有最新版本和所有修订版本。

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## 前言

MCS 010 2.0 版本是对 1.5 版本的一次重大更新。自 2019 年 09 月 24 日发布起可供参考。根据任何 MCS 产品标准获得微型发电产品认证的证书持有者均可从 2019 年 09 月 24 日开始着手执行此更新版本的标准。根据任何 MCS 产品标准获得微型发电产品认证的证书持有者均应从 2020 年 09 月 24 日起遵守此更新版本的标准。

## 1 简介

工厂生产控制 (FPC) 用于确保 MCS 认证的产品满足且持续满足适用的标准。本文件适用于 MCS 产品证书持有者。

## 2 范围

工厂生产控制系统评估是微型发电产品认证方案 (以下简称“方案” ) 中产品认证过程的一部分，本文件对其要求进行了定义。

## 3 定义

认证机构	根据 ISO/IEC 17065 合格评定，获得 UKAS 或其他等同的认可机构(即国际认可论坛 (IAF) 多边互认协议 (MLA) 的成员)认可的机构，并且根据本方案的要求对微型发电产品进行评估
申请者	向认证机构申请 MCS 微型发电产品认证的法人实体
MCS 产品证书持有者	此定义同样适用于想要获得 MCS 产品认证的申请者。在 MCS 产品证书中指定的或将包含的负责认证及其维护的法人实体。
MCS 认证的产品	成功通过 MCS 认证机构相关的 MCS 审批过程的产品
制造商联系人	每个生产制造场所的指定人员，其职责和权限包括确保质量管理体系所需过程的建立实施和维护。
代理人	MCS 产品证书持有者的指定人员，作为 MCS 产品证书持有者和认证机构之间的主要联系人

### 3.1 MCS 产品证书持有者的职责

MCS 产品证书持有者有责任确保满足认证的所有要求。尽管在 MCS 认证过程中可能需要涉及各方，但合规的最终责任在于 MCS 证书持有者。MCS 认证方案并没有规定可持有 MCS 产品证书的组织类型。可能性包括但不限于:产品制造商，产品设计者，产品品牌商。

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## 4 评价过程

### 4.1 初始评价

所有的评审都应该召开首次会议去检查评审的要求，识别健康和安全相关的风险，并且确认所需的设备。评审员应按照要求检查 FPC 过程的各个方面。任何发现不符合要求的项目都应提交不符合报告。不符合报告，连同所建议的纠正措施的细节(以及必要的客观证据)，应在评审之日起 45 天内送回审核。

每种技术类型的 MCS 要求可能包含额外的 FPC 要求，但至少应评估本文件附表 1 中的要求，以确认它们已得到满足并在每个相关场所运行。相关场所应由认证机构确定。

评审活动的结尾或者监督评审时应举行末次会议，确认评审的范围并识别所有不符合项。初始评审之后评审员应给出评审建议：FPC 要求已经满足但要在 45 天内解决所有不符合项，或者进行全面或部分重新评审。

### 4.2 认证的维护和监督

MCS 认证是通过监督评审和产品一致性审核测试或必要产品评估来维持和保持有效。根据上述 5.1 条款进行监督评审，以确保 MCS 认证产品的 FPC 系统持续的满足要求：

MCS 认证通过监督评估访问和满意地完成商定的产品审核测试或必要的产品评估来维持和保持有效。根据上述 5.1 进行监督评估，以确认 MCS 认证产品的 FPC 系统继续满足要求：

- 需在不符合项提出后 30 日之内提交证据关闭不符合项
- 当发现严重不符合项时，应在 12 周之内（非正常评审周期）进行重新评审，以检查纠正措施
- 若严重不符合项没有得到充分的纠正，相关的认证机构可能暂停认证

每个相关场所应开展周期性的监督评审（周期通常为一年一次），监督评审应在到期日之前 3 个月至之后 3 个月之间的时段内进行，即在认证的周年日。依据认证机构的判断，在某些情况下可以在正常评审周期之外进行附加的评审。

## 5 微型发电产品认证方案 (MCS) 要求的修订

微型发电产品认证方案 (MCS) 的认证方案要求将会通过发布修订版或修订案来修订，

具体内容将在网站 [www.mcscertified.com](http://www.mcscertified.com) 上公布

如果有影响产品或服务的批准或认证要求的技术或其他方面的变更，将会发行新版本的标准。轻微的或管理上的改变(例如更正拼写和印刷错误，更改地址和版权细节，增加澄清注释等)可以仅作为修订。

发行号将以十进制格式给出，整数部分给出发行号，小数部分给出修订的数量(例如发行号 3.2 表示该文件是第 3 版，有 2 项修订)。

本标准的使用者应确保拥有最新版本和所有修订版本。

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附录-表 1

序号	活动	要求
1.	评审联系人, 地址, 职责的细节	<p>在每一个生产制造场所都应有一名或多名人员 (制造商联系人) 负责以下工作:</p> <ul style="list-style-type: none"> <li>a) 确保质量管理体系符合 MCS 文件的要求;</li> <li>b) 确保生产过程提供其预期的输出;</li> <li>c) 报告质量管理体系的绩效和改进机会, 特别是向最高管理者汇报;</li> <li>d) 在策划和实施质量管理体系变更时, 确保质量管理体系的持续完整;</li> </ul> <p>MCS 产品证书持有者应指定两名代理人, 制造商联系人也可以是代理人 代理人应促进认证机构与每一个生产场所的生产联系人之间的联系</p>
2.	审核质量管理体系/质量计划	应当建立适当的质量管理体系, 包括为 MCS 认证的产品制定一个质量计划
3.	不符合项的决议	在之前 FPC 评审过程中识别的不符合项应在本 MCS 文件规定的时间框架内解决
4.	内部审核	应定期(至少每季度)召开会议, 审查每项 FPC 程序的运行并处理体系的所有问题, 会议、纠正措施及其实施均应保持适当的记录。
5.	文件控制	<p>应为所有的受控文件建立文件控制系统或程序:</p> <ul style="list-style-type: none"> <li>• 每一页都有其独特的标识, 页码和页数;</li> <li>• 应由有必要权限的人批准, 并发放到所有使用地点;</li> <li>• 删除所有有争议的/被替代的/作废的文件</li> </ul> <p>应建立文件化机制, 以确保所有相关国家和国际标准的适当的、通常是最新的版本可按要求获得。 注意: 可以接受电子形式的文件化程序。</p>
6.	客户要求及合同	<p>投标, 订单和合同应保留记录。此外, 合同评审系统应考虑以下内容:</p> <ul style="list-style-type: none"> <li>• 资源</li> <li>• 能力</li> <li>• 合同要求</li> <li>• 合同的修改</li> </ul>

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7.	采购	应建立文件化机制,记录设计、部件和材料的供应商(包括包装)。 记录应包括供方;身份、地址和联系方式以及部件和材料的详细供应信息。 应有一份供应商的总清单。另外,应建立文件化的机制用于管理供应商名单的添加和除名,包括对供应商的可持续发展进行必要检查的定义,如资金流动性、技术能力等。
8.	产品说明书评审	应建立文件化机制记录 MCS 认证产品规范。 应建立文件化机制,确保产品规范所有的变更及时传达给相关的 MCS 认证机构。
9.	生产控制	所有 MCS 认证产品应进行唯一标识,以便能够验证其作为 MCS 认证模型的状态。 包括确定生产日期和地点的方法,以便确定产品与 MCS 认证的关系。
10.	检查和过程测试	应制定在受控条件下进行检验和过程中测试的程序,包括: 来料检验-检查所有的部件和材料,以确保提供的部件/材料正确,数量正确。任何关键测量都应被识别,并应有检验记录,包括部件/材料的接受或不接受声明及其决定的依据。 过程中和最终检验——MCS 认证产品应在过程中和最终检验时进行检验,以确保满足标准或规范的要求。按照 MCS 011 进行测试的产品应经过此过程。来料检验、过程检验、最终检验和过程检验测试的结果应予记录。
11.	不合格品的处置	应建立文件化的程序,识别不合格的材料和零件(包括包装),将不合格品从 MCS 认证产品的生产线上移除并单独存放,以防止非预期的使用。 程序应识别必要的措施为被废弃的不合格材料,返工包括标签和授权要求。
12.	设备	工厂应有合适的设备进行生产控制、检验和测试测量。 该设备应进行适当的校准和标记,以表明其校准状态。 应保留相关的设备记录,每个记录应包括设备的描述(如压力计),唯一参考代码(如序列号),检查/校准的规模和频率,以及适当的客观证据,以证明设备能够满足规定测量所需的精度。
13.	储存,作业,包装和运输	MCS 认证产品和零部件的储存,作业,包装和运输应在受控的条件下实施,以防止非预期的损坏和变质。
14.	认证标志	MCS 标志应依据 MCS 品牌指南正确的使用。有效版本请见 MCS 官网 <a href="http://www.mcscertified.com">www.mcscertified.com</a>
15.	记录	应保存生产和检验记录,并由具有适当权限的人员定期检查(至少每周一次)。

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		应有机制记录每次检查的日期和由谁进行检查。 这些记录应在审查后至少保存两年或按欧盟监管要求保存更长时间。
16.	投诉	应建立投诉管理制度，对收到的任何投诉进行记录/登记，并采取纠正和预防措施以满足投诉要求在必要时投诉人的。所有投诉必须及时有效地处理。
17.	纠正/预防措施	应建立有效的纠正/预防措施程序
18.	培训和能力	所有参与 MCS 认证产品生产过程的人员，都应接受与实施的生产活动相关的、适当的培训。 应保留相关人员参与培训的记录，培训记录应包含活动和培训的详细信息。培训记录应标明培训机构，并由记录主体和培训机构双方签字。
19.	审核测试	根据认证机构的指示或方案的要求或相关 MCS 文件的详细说明，MCS 产品证书持有者应提供 MCS 认证产品的样品用于审核测试。样品应从最近或当前的生产中选取。所有选择的产品应交付给认证机构或指定的测试实验室。如果是品牌许可的产品，则可以在工厂中选择用于审核测试的样品。

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自发行以来的修订版本

文件版本号	修订细节	日期
1.1	删除认证方案名称中的“UK”； “BERR” MCS 标志代替“贸易和工业部门” MCS 标志	11/01/2018
1.2	增加修订细节	25/02/2008
1.3	作为被许可方添加 Gemser 详细信息； 文档重新格式化以反映品牌更新； 引用 BERR 更新为 DECC；MCS 标志相应更新； 以新的名称更新网站和电子邮件地址	01/12/2008
1.4	质量评审	10/01/2009
1.5	MCS 标志更新	25/02/2009
2.0	增加前言，范围和定义； 明确 MCS 产品证书持有者的职责； 工厂生产控制系统要求的附加信息； 重新命名文件，更新电子邮件和网站地址和外观的变化。	24/09/2019

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发行号 2.1

微型发电产品标准：MCS 011

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MCS 产品认证方案要求：

产品认证检测验收准则

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本微型发电产品标准为 MCS 慈善基金会所有，位于 Suite F40, Innovation Centre, Sci - Tech  
Daresbury, Keckwick Lane, Cheshire WA4 4FS. 注册慈善机构编号 1165752

本标准已获得微型发电认证方案的标准管理小组的批准。

### 微型发电标准修订

微型发电将会通过发布修订版或修订案来修订，

具体内容将在网站 [www.mcscertified.com](http://www.mcscertified.com) 上公布

如果有影响产品或服务的批准或认证要求的技术或其他方面的变更，将会发行新版本的标准。轻微的或管理上的改变(例如更正拼写和印刷错误，更改地址和版权细节，增加澄清注释等)可以仅作为修订。

发行号将以十进制格式给出，整数部分给出发行号，小数部分给出修订的数量(例如发行号 3.2 表示该文件是第 3 版，有 2 项修订)。

本标准的使用者应确保拥有最新版本和所有修订版本。

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# 前言

MCS 011 2.0 版本是对 1.5 版本的一次重大更新。自 2018 年 11 月 23 日发布起可供参考。根据任何 MCS 产品标准获得微型发电产品认证的证书持有者均可从 2018 年 11 月 23 日开始着手执行此更新版本的标准。根据任何 MCS 产品标准获得微型发电产品认证的证书持有者均应从 2019 年 2 月 23 日起遵守此更新版本的标准。

## 1 简介

本文件规定了申请人就首次产品认证、再认证、审核测试及扩展范围所提供的检测证据应用的验收标准。提供认证的认证机构可自行决定接受哪些检测的证据，但必须依据以下标准。

## 2 检测结果的验收标准

### 2.1 由独立的，且适用的检测项目获得英国皇家认可委员会 (UKAS) 认可或等同的认可机构认可的第三方检测实验室进行检测

如果检测项目将由或者已经由独立的，且适用的检测项目获得英国皇家认可委员会 (UKAS) 认可或等同的认可机构<sup>1</sup>认可的第三方检测实验室开展，则适用以下准则：

#### 2.1.1 检测结果必须记录在测试报告中：

- 使用英文（或者附上一份经授权的翻译版本）
- 由测试实验室完整、正确签署/授权，并确认满足所有适用要求
- 识别被测试产品的制造、型号和制造状态，并且详细记录任何修改的内容和/或为满足要求而进行的重复测试
- 检测报告的有效期为 4 年，如果由足够的证据证明检测报告持续有效则可以接受其超过 4 年有效期（例如：对生产过程的定期监督，审核测试等）

#### 2.1.2 此外，制造商应提供一份书面声明，说明所检测的产品是生产样品，并且能够充分的代表当前生产或识别对设计、生产工艺或材料的任何修改（这应在工厂生产控制(FPC)系统评估期间进行验证）

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<sup>1</sup> 作为欧洲认可合作组织(EA)或国际认可论坛(IAF)多边认可协议(MLA)成员的认可机构被视为等同于 UKAS

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2.1.3 如果测试的样品是原型, 或者已经进行了修改, 则认证机构应进行评估, 以确定这些差异/修改对测试结果可能产生的影响, 并确定是否需要进行进一步的测试或验证

2.1.4 如果具有类似设计、构造和功能的产品(即系列产品)的一项或多项要求特性相同, 则对一种产品这些特性的检测结果可应用于相关产品要求文件中定义的同一系列产品中的其他产品, 但须对本方法的有效性进行评估<sup>2</sup>。

## 2.2 由独立的, 且适用的检测项目未获得认可的第三方检测实验室进行检测

如果检测项目计划由独立的, 但是适用的检测项目未获得 UKAS 或其他等同认可机构认可的第三方检测实验室实施的, 除遵守上述 2.1.1 至 2.1.4 条款以外, 还需遵守以下要求:

2.2.1 认证机构应依据 ISO 170253 的要求对检测实验室进行评估<sup>4</sup>, 以确认该检测实验室有设备, 程序, 人员, 计量校准的状态和足够的能力去实施检测工作。评估包括现场见证相同或相似的检测、评审其他的检测报告和审核管理体系的相关信息, 以保证适当的程序管理且能够按照规定正确的执行

## 2.3 由独立的, 适用的检测项目未获得认可的第三方检测实验室进行检测, 且检测活动已经被执行

如果检测项目已经由独立的, 但是适用的检测项目未获得 UKAS 或其他等同认可机构认可的第三方检测实验室实施完成, 除了遵守上述 2.1.1 至 2.1.4 条款以外, 还需遵守以下要求:

2.3.1 检测实验室需提供适当的证据证明他们在实施检测项目时有合适的设备、程序、人员、计量校准的状态和足够的能力。认证机构应当评审这些证据并确定检测结果是否足够符合 2.2.1 条款的要求

## 2.4 由制造商的检测设备实施的检测活动

如果检测项目计划由独立的, 但是适用的检测项目未获得 UKAS 或其他等同认可机构认可的第三方检测实验室实施的, 除遵守上述 2.1.1 至 2.1.4 条款以外, 还需遵守以下要求:

2.4.1 认证机构应对其检测设备进行评估, 以确定该制造商有足够的能力去实施检测工作。对生产制造商的评估应至少包含以下项目:

- 应保留实施相关检测活动, 分析以及记录结果的适当的程序管理文档记录
- 具有符合适用标准的正确的检测和测量设备, 并且测试所需的所有测量设备均具有可追溯到国家标准的当前校准状态
- 有足够的手段来测量和控制试验区域的环境, 以满足标准所要求的条件

<sup>2</sup> 相似产品的检测结果的验收标准由认证机构自行决定, 但是建议在检测项目开始之前认证机构和制造商应对检测的计划达成一致

<sup>3</sup> EN ISO/IEC 17025:2005 实验室管理体系检测和校准实验室能力的一般要求

<sup>4</sup> 根据要求对检测实验室、制造商的检测设备, 以及测试的现场见证所产生的费用可能会由申请者承担

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- 测试人员应有足够能力、充分培训和测试经验，他们或他们的主管对检测设备、检测程序和被检测设备有足够的了解，能够理解所获得结果的重要性，并有权在发现不符合时采取正确的措施

2.4.2 认证机构应至少见证每个产品或系列产品所需检测的一个有代表性的样品，以保证所获结果的有效性和完整性。对于持续时间较长的测试，认证机构应至少见证检测的开始和/或结束阶段，并且检查测试条件的记录或收集的数据以评估结果的有效性和完整性

## 2.5 已经由制造商的检测设备实施的检测活动

在特殊情况下，在制造商的检测设备中已经进行的测试结果可能是可以接受的，前提是除了上述 2.1.1 至 2.1.4 中规定的条件外，还适用以下条件：

2.5.1 认证机构已对检测设备进行了评估<sup>5</sup>，确认制造商有能力进行测试工作，并且有足够的证据证明测试工作进行时他们有这些足够的能力。对生产制造商的评估应至少包含以下项目：

- 应保留实施相关检测活动，分析以及记录结果的适当的程序管理文档记录
- 具有符合适用标准的正确的检测和测量设备，并且测试所需的所有测量设备均具有可追溯到国家标准的当前校准状态
- 有足够的手段来测量和控制试验区域的环境，以满足标准所要求的条件
- 测试人员应有足够能力、充分培训和测试经验，他们或他们的主管对检测设备、检测程序和被检测设备有或者曾经有足够的了解，能够理解所获得结果的重要性，并有权在发现不符合时采取正确的措施

2.5.2 制造商已提供产品上市期间的书面证据，并证明在此期间产品具有令人满意的跟踪记录，其性能或可靠性没有重大问题。

2.5.3 认证机构已见证至少一个有代表性的测试样本的复验，所获得的结果证实了原测试的有效性（即，在考虑了测试程序的预期不确定性后，复验的结果与原测试的结果进行了比较）

<sup>5</sup> 根据要求对检测实验室、制造商的检测设备，以及测试的现场见证所产生的费用可能会由申请者承担

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自发行以来的修订版本

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1.1	删除认证方案名称中的“UK”； “BERR” MCS 标志代替“贸易和工业部门” MCS 标志	11/01/2018
1.2	增加修订细节	25/02/2008
1.3	作为被许可方添加 Gemser 详细信息； 文档重新格式化以反映品牌更新； 引用 BERR 更新为 DECC； MCS 标志相应更新； 以新的名称更新网站和电子邮件地址	01/12/2008
1.4	质量评审	10/01/2009
1.5	MCS 标志更新	25/02/2009
2.0	增加前言； 明确测试标准； 更新条款引用，修订标题和格式，以提高清晰度	23/11/2018
2.1	重新命名文件，更新电子邮件和网站地址和外观变化	21/06/2019

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