Contents

1. Scope 范围

This Supplier Quality Standard is valid for all Suppliers delivering products to any company part of Handicare Group of Companies.

该供应商质量规范适用于所有为 Handicare 集团内任何子公司提供部件的供应商.

2. Purpose 目的

The objective of this Supplier Quality Standard is to determine the processes for continuous improvement of Supplier quality. Quality is the Supplier's ability to deliver products according to specification, at the ordered time and quantity and at the best value possible. This agreement defines the requirements and processes:

- *to be followed for obtaining approval prior to providing products to Handicare specified delivery site*
- *for continuous improvement, monitoring and feedback of quality performance*
- *to be followed detection of non-conforming products in production*

此规范的目的是通过定义供应商质量相关要求和流程, 确保供应商满足质量要求并持续改善. 这里的质量是指供应商在规定的时间,交付正确的数量和满足产品规格/标准的产品. 这些要求和流程包括:

- 批量生产前零部件需要认可
- 监控和反馈供应商质量表现, 持续改善
- 不合格品发现时的处理

3. Management Systems 管理体系

3.1 Quality Management System 质量管理体系

Handicare requires the Supplier to introduce and maintain a quality management system based on ISO 9001 (latest version), or equivalent third-party certification, recognized by Handicare, with the obligation to set a zero-defect goal and to continuously improve their performance.

The Supplier will notify Handicare for discontinuation, initial or renewal of certificate. Suppliers who are not certified according to ISO 9001 (latest version) or equivalent recognized by Handicare, shall present a plan to become compliant within one year.

Handicare 要求供应商导入和维护一个基于 ISO9001(最新版)的质量管理体系, 或是拥有业界公认的第三方认证机构的有效认证, 该体系需以零缺陷为目标且持续改善. 首次认证, 续证或者认可中止, 供应商都需通知 Handicare.
对于没有取得 ISO9001 认证的供应商, 供应商需要提供一年内获得有效认证的计划.

3.2 Environmental Management System

Suppliers must comply with all applicable legal regulations regarding the environment, including, but not limited to, EU, US, Canada. and strive to avoid all negative effects on humans and environment with an adequate organization and realization of environmental protection in the company.

Suppliers must provide corresponding certificates at Handicare's request.

The Supplier will notify Handicare for discontinuation, initial or renewal of certificate. Suppliers who are not certified shall present a plan to become compliant within one year to ISO 14001 or equivalent recognized by Handicare.

供应商必须符合所有环境相关的适用的法律法规, 包括但不限于欧盟, 美国,加拿大市场的法律法规. 在公司内部充足的规划和执行环境保护措施, 努力避免任何人身和环境方面的消极影响.

必要时, 按照 Handicare 要求提供对应符合性证明材料.

首次认证, 续证或者认可中止, 供应商都需通知 Handicare. 对于没有取得 ISO14001 认证的供应商, 供应商需要提供一年内获得有效认证的计划.

3.3 Health, Safety and Social Responsibility 安全和社会责任
Suppliers must comply with ISO 45001 (was OHSAS 18001) and, or locally applicable requirements for occupational health and safety, worker health and safety, child labor prevention, freedom of engagement, equal opportunity, inappropriate behavior prevention, excess work hours prevention and adequate employee compensation.

供应商必须遵循 ISO 45001 (之前的 OHSAS 18001) 符合本国本地的职业健康安全法律法规, 遵守当地关于平等工作机会, 不雇佣童工, 超时工作, 最低工资标准等劳动法规规定.

4. Approval for new and modified production parts 零部件认可
The scope of this agreement covers new developed parts and parts with modified design and/or significant modified production method, including production process, manufacturing site, components, and sub-tier suppliers, herein referred to as 'new or modified product/process'.

零部件认可范围包括新开发部件和设计变更或生产方式显著变更部件. 生产方式显著变更包括生产地变更和/或次级供应商变更.

4.1 Notification 通知
Any changes or modifications to approved parts and/or production process, manufacturing site, sub-contractor, requires the Supplier to formally notify Handicare and obtain authorization prior to implementation of these changes via the PPAP process QOP-472-03. Handicare will determine the Initial PPAP submission required and communicate to the supplier.

任何修改或变更产品或生产过程, 包括生产场地变更或次级供应商变更, 供应商都需要正式通知 Handicare, 在执行变更之前都需要通过 Handicare PPAP 流程 QOP-472-03 批准. Handicare 将决定 PPAP 提交的要求并通知到供应商。

4.2 Quality Plan 质量计划
The Quality Plan must address all points listed in the check list in Appendix 1.
Before Handicare approves products for production supply, the Supplier must ensure that products delivered will be 100% conforming to all drawings and purchase order requirements.

Quality Plan must be agreed and approved by Handicare before production supply is started. Approval to supply is issued by means of a signed Handicare PSW form, see PPAP GL-PPAP-001 Handicare PPAP document pack

质量计划需要包括所有附录 1 所列出的内容.

在 Handicare 认可零部件开始批量供应之前,供应商必须确保交付的产品 100%符合客户图纸和采购订单要求.
在开始批量生产前,质量计划需要得到 Handicare 批准. 批准的方式是 Handicare 会回签零部件提交保证书 PSW, 见 PPAP GL-PPAP-001 Handicare PPAP 文件包中模板。

4.3 Product / Process Control Plan 控制计划

Supplier will provide a Control Plan for each product/product family produced. The control plan template is contained within the PPAP GL-PPAP-001 Handicare PPAP document pack. This must detail all Quality Control processes used to ensure the quality of products shipped to Handicare. A control plan is the written description of the system for controlling parts and processes. The plan must detail the controls implemented at every stage of manufacturing, from receipt of raw material to the dispatch of finished product.

The Control Plan must be maintained throughout the product life cycle and is updated whenever systems and control methods are evaluated and/or improved and must be modified each time a corrective action is requested.
Initial Control Plan must be supplied to Handicare using the Handicare PPAP document pack.
Relevant quality data is to be retained for the product life cycle and for additional two (2) years as a minimum.
供应商需要针对每个产品/或一个系列产品提交控制计划. 控制计划模板包含在 PPAP GL-PPAP-001 Handicare PPAP 文件包中.必须明确所有质量控制流程以确保出货的产品满足 Handicare 质量要求. 控制计划是一个系统控制每个子件和生产流程的书面文件, 必须明确生产环节的每个阶段的控制方式, 从原材料接收到成品出货.
控制计划是一个动态文件. 在整个产品生命周期内当控制方式经过评估和/或改善后,特别是当有纠正措施导入时,需要更新.
初始控制计划需要用 Handicare PPAP 包中模板提交.
相关的质量数据和记录保存时间为整个产品寿命周期再加至少 2 年.

4.4 Critical to Quality Characteristics 关键质量特性

Critical To Quality (CTQ) characteristics are those features for which variation outside of the tolerance could reasonably be expected to affect product safety, customer satisfaction, fit and/or function and are described on the drawing as such by the design-responsible entity (Supplier, where co-designing is applicable or Handicare).

At the beginning of the project, the Supplier shall investigate, confirm, and document the manufacturing feasibility of the proposed CTQs including risk analysis. Risk analysis demonstrated by producing a PFMEA (Process Failure Mode & Effects Analysis) document that is aligned to the stated Control Plan. If the Supplier is not able to meet the requirements the Supplier shall inform Handicare.

Suppliers must demonstrate initial capability of all CTQs by means of capability studies. CTQs must be controlled by means of SPC or another recognized method of on-going surveillance, upon request.

All CTQs shall have capability studies performed at least once per year with the results recorded on the Control Plan, unless explicitly stated otherwise.

For a PPAP submission, the supplier shall perform an initial 30-piece capability study on all CTQ features unless otherwise directed by Handicare R&D. Refer to the PPAP submission packs, PAR document.

For a PPAP submission that has no CTQ features identified, Handicare R&D can ask for an initial 30-piece capability study on features they considered as critical to this process or component. Refer to the PPAP submission packs, PAR document

The capability study and SPC results for CTQs must demonstrate a Cp/Cpk capability of ≥ 1.33. Results less than 1.33 requires the Supplier to:

- *Do 100% inspection before shipment.*
- *Take corrective actions.*

The Feasibility questionnaire, PFMEA (Process Failure Mode & Effects Analysis) template, and the Process capability template are contained within the Handicare PPAP document pack for the supplier to complete. However, Handicare will recognize the use of a suppliers own PFMEA and Capability Study templates when supplied for review or inserted into the PPAP document pack

关键质量特性指的是那些如果出现偏离公差合理预期会影响产品安全,客户满意度, 组装或功能的质量特性/参数. 设计人员会在图纸上对应标示 (适用时,供应商和 Handicare 协作设计).

在项目开始之初, 供应商应对关键质量特性实现的可行性包括风险分析进行研究,确认和记录. 风险分析应通过 PFMEA（过程失效模式和影响分析）进行并保存记录，并与对应 Control Plan 一致.
如果供应商不能满足要求, 应通知 Handicare.

供应商需通过过程能力研究证明所有关键质量特性的初始过程能力. CTQs 必须通过 SPC 或某种公认的持续监测方法控制。
所有关键质量特性的过程能力分析每年至少进行一次, 将结果记录在相应的质量记录里. 除非有同意排除.

PPAP 提交时，供应商应对图纸中标明的所有 CTQs 抽取 30pcs 进行过程能力分析，除非 Handicare R&D 有另外指定，参照具体 PPAP 包中的 PAR.
对于图纸中没有标识 CTQs 的， Handicare R&D 可以指定他们认为关键的项目，供应商应对这些指定的项目进行 30pcs 过程能力分析，参照具体 PPAP 包中的 PAR.

关键质量特性的过程能力必须满足 Cp/Cpk 大于等于 1.33. 如果 Cp/Cpk < 1.33, 供应商必须对此特性进行出货前 100%的检验, 且分析原因采取措施以提高其过程能力.

可行性分析， PFMEA 和过程能力研究模板包含在 Handicare PPAP 包中供供应商使用. 然而，Handicare 也接受供应商使用自己的相应模板.

4.5 Measurement Systems Analysis (Gauge R&R) 测量系统分析

When requested by Handicare, measurement systems used by Suppliers must be analyzed by conducting gauge variations studies to determine if the gauge is acceptable for its intended use. The criteria for acceptance are dependent upon the percentage of part tolerance used by the gauge system error.

当 Handicare 需要时,供应商应进行测量系统分析.测量系统分析的接受标准如下:

Under 10% error	*10%以下*	*Good Accuracy*	*良好*
10% to 30%	*10%到 30%*	*Acceptable*	*可接受*
Over 30%	*30%以上*	*Not Acceptable*	不可接受

4.6 PPAP/ FAI (First Article Inspection) 首样

For all new or modified product/ processes, the PPAP requests a minimum 5 parts for FAI (First Article Inspection), unless explicitly stated otherwise. The measurement of the FAI samples shall be conducted at the site of final production, at production rate, using final tooling, gauging, production process, production materials, serial tooling, and production operators. Products produced must meet all requirements. Handicare reserves the right to be present during the initial run.

对于新产品或变更的产品/流程，需要首样确认.首样确认需要至少 5 个样品，除非有其他说明. 该首样需要来自于正常生产，以正常生产的速度,用最终的工装/治具，正常生产流程，正常生产原材,正常生产工具和员工. 首样生产必须满足所有质量要求. Handicare 保留对首次生产进行现场确认的权利.

4.7 Approval process 审批流程

For all modified product/process the Supplier notifies Handicare as indicated in paragraph 4.1.
For all new product and all approved product/process modifications, the Supplier delivers the required documents as described in appendix 1, unless specifically stated in writing by Handicare.

对于所有产品或流程的变更,供应商必须先通知 Handicare.
对于新产品或批准的产品/流程变更,供应商需要按照附录 1 提交对应的资料给 Handicare，除非有其他 Handicare 的书面说明.

Approval for delivery is given by means of a PSW. A PSW can be:
总终批准出货是通过回签 PSW 零件提交保证书. PSW 可以有以下结论:

- *Rejected* 拒绝:
  - *Handicare informs the Supplier of the reasons for rejection*
    Handicare 会告知供应商拒绝的原因
  - *After solving the root-causes the Supplier submits new/revised PPAP document pack.*
    解决问题原因后,供应商需要重新提交 PPAP 资料/样品
- *Approved for supply*. 同意

- Temporary Approval is controlled by the Handicare concession request process 临时同意，通过 Handicare 让步申请流程
  - Handicare informs the Supplier of the reasons for rejection. The supplier with the guidance of Handicare can supply product or provide services after the submission of and Handicare approval of a concession request. Once the application has passed through the concession validation process, product or services can be accepted by Handicare. The part delivery paperwork must state the concession number. This is a temporary action while the supplier identifies solution and implements a corrective action package with a view to re-submit a revised or new PPAP submission pack.
    Handicare 会告知供应商不良的原因. 供应商需提交让步申请，得到批准后,按照 Handicare 的指示提供产品或服务. 一旦让步接受申请被验证可行，Handicare 可以接受提供的产品或服务. 相应的出货文件必须注明让步接受编号.
    这是一个在供应商寻找解决方案期间的临时措施. 一旦有效的改善措施到位，需要重新提交新的 PPAP.

- All initial improvements, where possible, must have an increase in surveillance and be supported by data. All improvements made need to be captured and recorded on a revised control plan and be part of a revised PPAP submission
  在可能的情况下，所有初步改善措施都必须增加监测，并有数据支持.
  所做的所有改进都需要体现并记录在修订的控制计划中，并成为修订后的 PPAP 提交的一部分

4.8 Sub-tier management 次级供应商管理

For all new and modified product/process the Supplier will ensure all sub-tier Suppliers follow the same processes as mentioned above and approve all sub-tier Suppliers by means of the Handicare PPAP process. Handicare is entitled to receive sub-tier quality documentation upon request and reserve the right to audit the sub-tier Supplier together with the Supplier.

The Supplier shall identify customer needs, expectations and demands. The Supplier assures the cascading of Handicare's requirements to the sub-Suppliers and conducts quality reviews as appropriate.

对所有新零件和产品/过程变更, 供应商需确保所有次级供应商遵循上述相同的流程, 并且通过类似的 Handicare PPAP 流程认可所有次级供应商. Handicare 有权要求获得次级供应商的质量文件, 保留和供应商一起审核其次级供应商的权利.
供应商应识别顾客的需求，期望和要求。供应商要确保其次级供应商理解满足 Handicare 的要求, 必要时进行质量评审.

5. Continuous improvement of quality performance 持续改进

In line with ISO 9001, Handicare expects the Supplier to improve quality performance on continuous basis. Objectives and action plans will be defined annually between Handicare and the Supplier, and Supplier quality performance will be communicated on a regular basis to the Supplier.

与 ISO9001 一致, Handicare 期望供应商持续改善其质量表现. Handicare 和供应商将每年检讨年度目标和行动计划, Handicare 将和供应商定期沟通其质量表现.

6. Non-conforming product 不合格品处理

In the event of non-conforming material, component or systems detected, Handicare will determine, in cooperation with the Supplier, the best method of securing material, component or systems to meet production requirements. This can be:
当发现不合格材料/零件或组件时,Handicare 将同供应商协作,确认最好的处理方式. 这些方式包括：

- *Handicare to return the entire lot of defective material, component or systems to Suppliers*
  Handicare 将整批不合格物料/零件/组件退回给供应商
- *Suppliers to sort the rejects at Handicare site*
  供应商到 Handicare 工厂分选
- *Handicare personnel to perform sort/rework at the Supplier's expenses*
  Handicare 执行分选/返修，成本由供应商承担
- *Handicare to identify an external resource (certified by Handicare Quality department) to perform the sort/rework at the Supplier's expenses*
  Handicare 指定第三方资源（由 Handicare 质量认可）进行分选/返修，成本由供应商承担

Handicare will collate all the associated disruption costs and charge the value back to the supplier.
Handicare 将收集整理所有相关的损失成本，向供应商索赔

The Supplier take immediate action to:
供应商需要立即采取行动：

- *Prevent more non-conforming product entering Handicare's production lines and contain the full supply chain.*
  预防有同样风险的不合格品进入 Handicare 产线，需考虑整个供应链上的风险品
- *Ensure proper labeling of repaired and/or suspect products and conforming parts for X time.*
  及时区分标示清除维修品, 怀疑品,良品
- *Implement actions to solve root-causes and prevent the root-cause from happening again in the same product or similar products from the same or other production lines; detailed actions shall be reported on the Handicare 8D report, and a control plan will be updated.*
  进行原因分析，采取纠正措施，采取预防措施防止类似问题再次发生，采取预防措施防止类似产品/过程出现问题; 详细的改善措施需以 Handicare 8D 的方式提交，控制计划需要更新

7. PPM and MPM Supplier rating 不良率和不良交付率
PPM performance is monitored using a 3-month rolling PPM measurement. Objectives will be set by Handicare every year as part of the Supplier's continuous improvement plan.

PPM 和 MPM 表现采用 3 个月滚动的方式统计，每年 Handicare 会设定目标推动供应商持续改善。

8. Preventative Maintenance Plan 预防维护保养计划
Suppliers will keep their preventive maintenance plan for all equipment involved in the fabrication of the material, component, or system in question, at Handicare's disposal.

Life progress of tooling to be reported at regular intervals and in a timely fashion to secure continuous supply. Any defects must be reported to Handicare as they occur.

供应商需制定所有生产设备的预防维护保养计划，并保存执行的记录.
为确保供应不中断，模具的使用寿命进度需要及时定期汇报给 Handicare。任何模具异常需及时告知 Handicare.

9. Quality records 质量记录
Quality records shall be stored and maintained in such a way that they are readily retrievable in facilities that provide suitable environment to minimize deterioration or damage and to prevent loss. Quality records content and required storage period to be established between Handicare and the Supplier, records shall be made available, for evaluation by Handicare.

质量记录需妥善保存，避免损坏或遗失，且在需要时容易获得. Handicare 和供应商可以协商确定质量记录内容和保存期限。需要时，供应商需提交指定质量记录给 Handicare 评估。

10. Glossary 术语
RoHS : Restriction of Hazardous Substances 欧盟《关于限制在电子电器设备中使用某些有害成分的指令》

REACH: : Registration, Evaluation, Authorization and Restriction of Chemicals 欧盟法规《化学品的注册、评估、授权和限制》

PSW : Part Submission Warrant 零件提交保证书
CTQ : Critical to Quality 关键质量特性
SPC : Statistical Process Control 统计过程控制

Cp/Cpk : Process Capability 过程能力
Gauge R&R : Gauge Repeatability and Reproducibility 测量系统重复性再现性分析
PPAP : Production Part Approval Process 生产件认可程序
FAI : First Article Inspection 首件检验
PPM : Parts Per Million 百万分之, 衡量不良率
MPM : Mis-deliveries Per Million 百万分之, 衡量不良交付
PFMEA : Process Failure Modes and Effects Analysis 失效模式及影响分析
AAR : Appearance Approval Report 外观认可报告
MSA : Measurement Systems Analysis 测量系统分析
8D : 8 Disciplines methodology in problem solving 8 个原则法, 问题解决的一种思路和方法

Appendix 1: Quality Plan requirements 质量计划要求
The following items must be submitted and/or retained:
如下表格列明了具体需要提交和/或保留的质量记录/文件:

Quality Plan Requirements 质量计划要求	Submit 提交	Retain 保留
1. Design Records 设计记录		X
2. Engineering Change record (where applicable) 工程变更记录		X
3. PPAP documentation PPAP 文件		X
4. Concession Request form 让步申请单		X

❑
The following Handicare Quality forms / templates are available on Handicare's website (under 'Supplying to Handicare'), and upon request to Handicare Quality.
下列质量表单和模板可以在 Handicare 管网" Supplying to Handicare"获得,或联系对应的 Handicare 质量窗口.
http://www.handicare.com/en/about-handicare/supplying-to-handicare.aspx

PPAP GL-PPAP-001 Handicare PPAP document pack
Templates contained within the PPAP document pack are…

- PAR (Part Approval Request and Requirement, PAR) 零件批准需求和要求 (PAR)
- Feasibility 可行性分析
- Drawing and Specifications 图纸和规格书
- Process Flow 流程图
- PFMEA template –失效模式及影响分析
- Control Plan 控制计划
- First Article Inspection FAI
  - (FAI - FORM-1) 首样检验（FAI -1) Part Number Accountability. 部件认可责任
  - (FAI - FORM-2) 首件检验 (FAI -2) Product Accountability, Materials, Special Processes & Functional testing 产品认可责任 - 材料、特殊工艺和功能测试
  - (FAI - Form-3) 首件检验 (FAI -3) Characteristic Accountability, Verification & Compatibility Evaluation 特性认可责任、验证和兼容性评估
  - FAI Appendix Sheets 首样检验附件
- Process Capability Analysis 过程能力分析
- Appearance Approval Report (AAR) 外观批准报告（AAR）
- Material Certification 材质证明
- Packaging Approval 包装批准
- Part Submission Warrant (PSW) 部件提交保证 (PSW)

Additional PPAP templates within the pack to be completed if required by Handicare if required

- MSA template –测量系统分析
- Checking Aids 检查辅助工具
- Qualified Laboratory Certification 合格实验室认证
- 8D-report template –纠正预防措施报告
- Concession Request form 让步申请单

1.0 DOCUMENT CHANGE & COMPETENCY REQUIREMENTS

DCR Number	Revision	Competency Requirements
		☒ Read & Understand Only ☐ Computer Based Training ☐ Competency Assessment ☐ Work-based Assessment

2.0 DOCUMENT APPROVAL

Process Owner		Quality Representative	
Name:	Emma Bowker	Name:	Richard Jack
Signature:	EBowker	Signature:	
Date:	10-09-2023	Date:	10/09/2023

Acknowledgement by Supplier

Name……

Signature……

Date……