EF-1126

Supplier Quality Agreement

The purpose of this Supplier Quality Manual, Appendix A, attached "Quality Manual" is to define the framework within which Invacare wishes to work with its partners.

The **medical device market** requires Invacre and its partners to be compliant with regulatory requirements and Quality control of the products, the components or services distributed.

The control of quality assurance is an approach allowing to control the quality at the different stages of the products distributed including the design, the industrialization, the manufacture and the use of the products.

Invacare suppliers play an important role in this process and contribute directly to the quality of the products provided to its customers and patients.

Compliance with the rules defined in this manual makes possible the establishment of an effective and trusting collaboration having for final objective the continuous improvement and control of competitiveness.

1. Scope: This manual is applicable to all purchase orders and will be referenced in any contract.

2. Quality System: Supplier will establish (define, document, implement and maintain) a Quality System that satisfies the level of risk and complexity associated with the related finished medical devices, product, part or services.

3. Production Part Approval Process: Prior to starting normal production, the supplier shall submit Part / Product evaluation and approval documentation according to level defined by INVACARE. Verification of applicability and capability shall be provided. Prior to starting normal production, the supplier shall submit samples of the product / part produced under normal production conditions in agreed quantities and on schedule. Normal production may not be started until it is released in writing by INVACARE.

4. Quality Record Retention: Supplier will maintain appropriate quality records related to the design and production of FMD's, product or part delivered to INVACARE for a minimum of 10 years after last shipment, unless a longer period is requested by INVACARE. Unless otherwise instructed by INVACARE, such records include batch records, non-conformity records, calibration reports, incoming- in process, end of line inspection and process validation records. At the end of the required retention period, Supplier will contact INVACARE to determine the appropriate disposition of the records (e.g., send to INVACARE, destroy).

Date Signature

5. Change Request Notification: Prior to making any product, material or process changes that may affect form, fit, or function of any FMD, product, part or service that Supplier delivers to INVACARE, Supplier must submit a written change request to INVACARE (including reason for the change, specific details of the change, part number and cost related). Products affected by such changes must not be delivered to INVACARE until Supplier has received INVACARE's written approval of such change request, which will not be unreasonably withheld. INVACARE will decide on the change at that time and either accept or deny the change. If the change impact a new material, Supplier will provide full technical specification of the new material to be used. Supplier will issue Supplier Acknowledgment and details about the execution of the change (Execution date, implementation, serial number of first implementation, cost and availability of first samples, back compatibility, product functionality and reliability).

6. INVACARE change; In case INVACARE requests a change, Supplier will review the new information received and inform INVACARE without delay about inconsistencies or failures. If supplier finds the data correct he will issue supplier acknowledgment and details about the execution of the change (Execution date, cost and availability of first samples, back compatibility).

Date Signature

7. Nonconformance: If INVACARE notifies, via Supplier Corrective Action Requests (SCAR), Supplier of a product nonconformance and requests Supplier to investigate such nonconformance, then Supplier will, within 2 working days of receiving such request, respond to INVACARE in writing (e-mail or post mail) with a plan to investigate and correct such affected products; the preferred format of such plan is an 8D report or equivalent. Supplier will conduct root cause investigation within 5 working days. Implement corrective and / or preventive actions within 10 working days. Supplier will complete its investigation within 30 working days of receiving such request, unless both Supplier and INVACARE agree in writing to a longer period. In the event of nonconforming products / parts are discovered at any state in the process or in the market Supplier will assume responsibility for the costs incurred by INVACARE and/or its customers because of the non-conformance. These costs may include but are not limited to:
    - Testing, inspection, and sorting as required
    - Process changes which become necessary in order to remedy nonconformity
    - Recall costs
    - Travel incurred
    - Cost of Product(s) or additional material impacted by the non-conformity
    - Support costs that are directly related to the resolution of the non-conformity
    - Any external analysis

   If Supplier discovers that nonconforming products were shipped to INVACARE or its customers, then Supplier will inform INVACARE immediately of such discovery by providing serial or batch number, type of defect and containment action taken and corrective action.

8. Cooperation: Supplier will cooperate with INVACARE and provide all information reasonably requested by INVACARE to support INVACARE in its compliance with applicable laws and regulations, or internal procedures related to the sale and use of INVACARE products, or customer complaints and recalls.

9 New Product Initialization (NPI) Process: All major product developments at INVACARE are managed through a stage gated approach. Team meetings with the Supplier will be held during which Supplier requirements will be defined and communicated. Minutes of Meeting shall be established and approved by both Parties.

10 Performance Monitoring: INVACARE monitors Supplier key indicators to be able to track supplier performance. The Supplier must maintain real time measurement and feedback process performance tools in efforts to achieve a delivered quality in accordance with the Performance Evaluation goals. The Supplier must maintain objective evidence of this activity and report per established communication plans with Customer.
Supplier can be required to support weekly/monthly dashboards including but not limited to the following topics:
- Yields
- Quantity produced and Out-of-Box Audit (OBA) defect rates (PPM)
- Incoming / Inspection defect rates at supplier (PPM)
- Process Capability calculations (i.e. Cp, Cpk etc.)
- Supplier Corrective Action Performance
- NPI build status
- Pareto charts of production defects
- Analysis information from any on-going reliability failure(s) (e.g. 8D reports and follow up)

Date Signature

11 Recalls: If it is necessary to recall (including corrections in the market) any products delivered to INVACARE due to instructions of the relevant governmental authority, or the reasonable decision by INVACARE for the safety, quality, commercial or technical reasons; then INVACARE will give Supplier as much notice as reasonably possible of such recall or withdraw. The parties will, in good faith, discuss remediation measures and agree on necessary retrofit or recall actions. Supplier will not release any statement, information or publicly refer to any INVACARE recall or withdraw without the prior written approval of INVACARE. Supplier will not negotiate with third parties in the name of INVACARE unless explicitly told to do so in written form. When the supplier is the holder of any market authorization (e.g. Declaration of Conformity) and is forced by circumstance or law to recall products then Supplier will inform INVACARE within 1 business day of such a decision.

12 Documentation Control: Supplier assures traceability which product was produced to which requirements (e.g. Drawings) by INVACARE. Supplier will review all such documentation for obvious errors, manufacturability and completeness. In case of findings Supplier will inform INVACARE. Supplier will inform INVACARE about receipt and acceptance of such documentation. Supplier will ensure that all INVACARE documentation is controlled and distributed, with the correct revision level, to the appropriate personnel that produce the product or service for INVACARE, including Supplier's sub-suppliers that use INVACARE's documentation.

13 Quality and Safety Reporting: Supplier will maintain a documented reporting system for notifying INVACARE when Supplier has knowledge of any product issue related to safety or quality that requires an immediate stop-shipment or recall of Supplier's product that has or will be delivered to INVACARE. Such report shall be submitted 1 business day after discovery.

14 Audits: INVACARE, or its third-party representative, may audit Supplier's Quality System, quality control and/or manufacture of the product at Supplier's facilities at reasonable times with advance written notice to Supplier. Supplier will cooperate with INVACARE and provide INVACARE with relevant documents relating to Supplier's Quality System, product manufacture and manufacturing processes. Upon receipt of INVACARE's audit findings, Supplier will submit planned or completed corrections for any findings within 10 working days. INVACARE will review and provide feedback within 10 working days. In case of INVACARE's rejection of Supplier's correction plan, Supplier to adapt the correction plan to address INVACARE's concerns within 10 working days from INVACARE's rejection.

15 Packaging and labelling: Supplier shall ensure that the goods are packed, stored and transported using suitable means of transport in order to avoid damage, contamination, loss and reductions in quality. The means of transport must be labelled so that their contents are always identifiable. The supplier must ensure that the labelling of the packaged products is also identifiable during transport and storage. The labelling must contain the following details: item number, INVACARE order number and quantity. Deliveries which contain products with different item numbers must be supplied with a clear separation of the items. All packaging material must be environmentally friendly and recyclable as much as reasonable. Packaging which creates a lot of waste and combinations of different materials should be avoided.

Date Signature

16 Safety and environmental Regulations: Supplier commits to comply with local legal regulations regarding the environment, health and, occupational, and to strive to avoid all negative effects on humans, products and environment by an adequate organization and realization of environmental-, health and, occupational protection preventive actions in the company. For this, the implementation and further development of an Environmental and Occupational Safety Management System is beneficial.

17 Reach, RoHS and Conflict Minerals: Supplier is obligated to fulfil the requirements of the RoHS Directive 2011/65/EU and the REACH regulation (EC) no. 1907/2006. If there is an exception for these requirements available, this must be clearly communicated to INVACARE in writing for every single case. Suppliers who manufacture components, parts and/or products containing 3TGs (Tin, Tantalum, Tungsten or Gold) are required to source these minerals from smelters whose due diligence practices have been validated by the Conflict-Free Smelter Program (CFSP) or an independent third-party audit program. INVACARE expects its suppliers to work with their own sub-suppliers to obtain smelters information and to ensure that they are sourcing these minerals from environmentally and socially responsible suppliers. A Conflict Minerals Reporting Template (CMRT) shall be provided to INVACARE upon request. Suppliers are expected to record and maintain traceability data for 5 years minimum.

18 Code of conduct for suppliers: INVACARE expect it's suppliers to comply with the applicable laws and regulations of the countries in which they operate and to conduct their operations in an ethical, socially and environmentally responsible manner. Areas includes but are not limited to:

- **Child Labor**. INVACARE does not tolerate child labor in our supply chain. Suppliers shall avoid any child labor in their business operations in accordance with the ILO's core labor standards, applicable laws and regulations.
- **Human Trafficking or Slavery**. Suppliers, including sub-suppliers, shall not engage in activities or support of human trafficking or use of slave labor, directly or indirectly.
- **Freely Chosen Employment**. INVACARE does not tolerate any forced, bonded or involuntary prison labor. Workers shall not be not required to lodge "deposits" or their identity papers with the employer and are free to leave their employer after reasonable notice.
- **Free Association.** Supplier shall respect the rights of employees to freely associate and bargain collectively.
- **Regular Employment**. To every extent possible, work performed must be on the basis of a recognized employment relationship established through national law and practice.
- **Wages and Benefits**. Employee wages and benefits paid for a standard working week shall, at a minimum, meet the applicable national legal standards or industry benchmarks. In any event, wages should always be sufficient to meet basic needs and to provide some discretionary income. All employees shall be paid in a timely manner. Supplier should provide to employees written and understandable information about their employment conditions with respect to wages before they enter employment, and about particulars of their wages for each pay period. Unless otherwise provided by local laws, deductions from wages as a disciplinary measure shall not be permitted. All disciplinary measures should be recorded.
- **Working Hours**. Working hours shall comply with the national laws and benchmark industry standards, whichever affords protection. Overtime shall be voluntary, shall not be demanded on a regular basis and shall always be compensated at an agreed-upon higher rate.

Date Signature

- **No Discrimination**. There shall be no discrimination in hiring, compensation, access to training, promotion, termination or retirement based on race, caste, national origin, religion, age, disability, gender, marital status, sexual orientation, or political affiliation. Supplier shall promote equal treatment of all employees.
- **No Harsh or Inhumane Treatment**. Suppliers shall provide their employees with a workplace free of harsh or inhumane treatment. Physical abuse or discipline, the threat of physical abuse, sexual or other harassment and verbal abuse or other forms of intimidation shall be prohibited

The following Sections are also applicable if Supplier is manufacturing "Finished Medical Devices," as defined by the European Union, U.S. Food and Drug Administration, Health Canada, or any other region of the world where INVACARE intends to sell such devices.

19 Registrations: Supplier will apply for and maintain all required registrations needed to be a manufacturer of such devices according to local legislation.

20 Quality System: If supplier supplies Finished Medical Devices to the EU Supplier will establish a Quality System that satisfies the applicable sections of Regulation (EU) 2017/745 (MDR) (with certification to ISO 13485 (current version) a plus) and / or 21 CFR Part 820 if the target market is the USA.
Other target market need to be specified in writing at the time of project start with Seller.

21 Outsourced processes: Supplier shall retain responsibility of conformity to International Standards, customer and applicable regulatory requirements for outsourced processes, at sub suppliers as well as at INVACARE. Typical outsourced process at INVACARE can be local adaptations, adding / removal of user manuals / -information's, adding and assembly of accessories onto delivered FMD. Supplier to agree / define ways of control over such INVACARE processes. Control can be via work instructions developed by INVACARE or Supplier, Inspection- / release instructions developed by INVACRE or Supplier, product - / process audit programs. Supplier shall keep adequate records to enable INVACARE to assure appropriate processing. Especially after changes it shall be recorded when such changes have been inserted (e.g. Serial Number).

22 Compliance with Finished Medical Device Laws and Regulations: Supplier will maintain compliance with all laws, directives, and related regulations and standards that apply in the manufacturing and delivery of its products, including reporting, record keeping and product testing applicable to the manufacture of FMD, and electromagnetic compatibility for all products delivered to INVACARE. Such laws may include, but are not limited to, Council Directive 93/42/EEC / Regulation (EU) 2017/745, and from 2020 May 20th Medical Device Regulation (EU) 2017/745, applicable parts of FDA's regulations in 21 CFR Parts 800 to 898, and other country medical device laws, regulations and directives. INVACARE will outline with each FMD which regulations apply. If the supplier is a Medical Device manufacturer in its own right (Invacare is in the role of Importer and /or Distributor) Supplier will assure appropriate Market access as demanded by Invacare. In the EU this will be a Declaration of Conformity and a EU Authorized Representative.

Date Signature