

QUALITY MANAGEMENT GUIDELINE

Preamble

This quality management agreement („**Agreement**“) is an indispensable part of the delivery contract with MONTRATEC and its affiliated companies. The Agreement describes and regulates all quality management measures provided between MONTRATEC and the SUPPLIER.

This Agreement applies to all products and services delivered by the SUPPLIER based on an order. Moreover, individual quality management measures can be agreed upon between MONTRATEC and the SUPPLIER.

1. Quality management

The SUPPLIER administrates a certified or DIN EN ISO 9001 –orientated quality management system, and will fabricate and test the products according to these rules, with the obligation of a zero error objective and the permanent improvement of its services.

The SUPPLIER must present his quality documents on his own responsibility to MONTRATEC and must inform MONTRATEC immediately about updates or the withdrawal of a quality certificate. Sector and/or material specific requirements (for example, but is not limited to, FDA, GMP) have to be proven additionally.

2. Environmental management

When important environmental processes are carried out, especially systems that require approvals, the introduction of an environmental management system according to ISO 14001 is recommended. The SUPPLIER identifies his important environmental aspects, for example, but is not limited to waste, water consumption, waste water, emissions etc., and carries out permanently improvements in these areas.

Moreover, the SUPPLIER commits himself to respect the legal regarding environmental protection.

3. Audits

In order to be able to assess the efficiency of the quality management system regarding the process of the company, MONTRATEC reserves the right to carry out audits at the SUPPLIERS' site at least once a year and whenever necessary.

At this regard the SUPPLIER will grant MONTRATEC, in a reasonable scope and after previous consultation, access to the required company divisions. The SUPPLIER will be informed in writing by MONTRATEC about the results of the audit and the registered potential improvements.

4. Specification

The products must match to agreed description (for example, but is not limited to, order texts, specifications, information sheets, drawings, specifications) and/or the agreed samples. The SUPPLIER must check immediately whether a description presented by MONTRATEC is faulty, unclear, incomplete or does not match the sample.

5. First Sample

Before the first supply in series of a product the SUPPLIER, upon explicit request of MONTRATEC, has to present first samples. First samples are subject to a complete check; this means that all project specific quality features agreed in writing with MONTRATEC are checked by the SUPPLIERS, in order to prevent errors before starting the series production and to check whether the agreements have been fulfilled.

The results must be documented by the SUPPLIER in a first sample report (“**EMP**“) and have to be added to the supply of the first sample. The assignment of the first sample and his test features for the corresponding EMPB has to be clear.

The series production will only start after the written first sample approval by MONTRATEC.

6. Evidence & information

Before modification of the production processes, materials or purchase parts for the products, displacement of production sites or other quality relevant measures, the SUPPLIER must inform MONTRATEC in due time so that MONTRATEC can check whether the modifications have a negative impact on quality.

When the SUPPLIER detects a deterioration of the quality, the SUPPLIER will inform MONTRATEC immediately at this regard and will take the appropriate remedies. The SUPPLIER must document all quality management measures, specially measuring values and test results. The obligation to file the documents and measurements as well as possible samples is at least 15 years.

7. Delivery & incoming goods inspection

The supplier delivers the products according to the packing and delivery conditions of MONTRATEC (which can be viewed under www.montratec.com), in appropriate transportation means, in order to avoid quality problems (for example, but is not limited to, contamination, corrosion, etc.).

The incoming goods inspection at MONTRATEC is limited to external recognizable transportation damages as well as the quantity and identity of the ordered products. Possible defects must be communicated in due time, however within two (2) weeks.

8. Complaints & measures

If MONTRATEC during the remaining production process determine defects, they will be communicated to the SUPPLIER by means of a defect report. At this regard, the SUPPLIER waives the objection of a delayed notification of defects.

The SUPPLIER will draft on demand of MONTRATEC immediately an error analysis in the shape of an 8D-report and will inform MONTRATEC about the immediate taken measures.

Depending on the problem, MONTRATEC will determine the procedure to be followed for the processing of the complaint:

- Return of the complete supply for analyses and repair or new production and immediate spare delivery by the SUPPLIER,
- Sorting of the goods and return of the defect products for analyses and repair or new production an immediate spare delivery by the SUPPLIER, or
- Sorting a repair by MONTRATEC.

9. Special release

The suitability of products with errors and defects which do not affect the functioning, maintainability or even the safety, can be approved after a thorough examination by MONTRATEC in writing by means of a special release. Special releases are no general releases and have to be approved and checked for each specific case. Consequently, they are limited for an agreed period of time or a supply volume. Special releases do not discharge the SUPPLIER from valid contractual obligations and do not imply either a general renouncement of guarantee and liability claims on behalf of MONTRATEC.

10. Product liability insurance

The SUPPLIER guarantees an appropriated protection by means of a product liability insurance with a cost of at least 5 million EUR for personal and material damages. Upon request, the SUPPLIER has to prove the insurance protection by presenting a copy of the insurance policy or in other way.

11. Final stipulations

Modifications and additional clauses of this Agreement have to be done in writing.

If a contract stipulation is ineffective or contains an omission, the effectiveness of the other stipulations will not be affected; in this case the contractors will agree an effective which will realise the foreseen aim. This also applies to omissions in the Agreement.

The Agreement is governed by the laws of the Federal Republic of Germany under exclusion of the United Nations Convention on Contracts for the International Sale of Goods (CISG) and the conflict of law jurisdiction for any disputes is the registered office of MONTRATEC.