|  |  |  |  |
| --- | --- | --- | --- |
| **Document title** | GS402A0051 Requirements for Ex Quality Management | | |
| **Document Type** | Group Standard | **Valid from** | 15-May-2024 |
| **Author** | GMHEPR | **Owner** | GMHISK |
| If this is a printed version (copy), the original can be foundin IMS/QMS/SC via Insite/Toolbox. | | | |

***Document history***

|  |  |
| --- | --- |
| ***Version*** | ***Changes from last revision and why*** |
| *16.0* | Addition of 4.1.2 Changes of Technical documents. |
| *15.0* | Deletition of GI402A0008-01 from References |
| *14.0* | GF402A0051-01 Supplier related DoC form added |

# Purpose

Products for application in potentially Explosive atmospheres – Ex marked products – must be approved and produced according to:

ATEX directive - to be allowed to be marketed and sold in the EU

IECEx requirements

FM “Quality Assurance guidelines”

This Group Standard states quality management activities to be implement in connection with production of Ex certified products.

The purpose is to ensure that products produced and sold as Ex products are in accordance with their Ex certificates.

This Group Standard only concerns the Extra requirements, which must be observed in addition to the requirements of the ISO 9001 standard.

# Scope

This Group Standard applies to **purchase, design, production, quality, sales and distribution of Ex certified products**, or parts for such products in production companies.

The Quality management system shall ensure that the Ex product conforms to the Type described in the certificate and technical documentation.

**In case of unclear regulation by this standard, the ISO 80079-34 international standard must be followed**.

# Responsibilities

**3.1** **Responsibility and authority**

The development management shall appoint an Ex Authorized Person and his/her substitute regarding every Ex critical product.

Responsibilities and Authority of the Ex Authorized Person(s):

* Coordinate Ex related activities for the product(s).
* Inform - with help of the Product Compliance team – the Notified Body about all considered modifications to schedule drawings and obtain approval from this Notified Body before the modification is carried through.
* Ensure - with help of the Product Compliance team - that the regulations (EU directive, IECEx schemes etc.) and standards which apply to the product(s) are monitored.
* Assess and approve considered changes on Related Drawings.
* Definition and marks of significant parts and critical parameters.
* Review and approve changes in all other technical documentation including sales literature and instructions (e.g. I/O manual) to ensure that these are in accordance with the Ex certificate of the product.
* Ensure customers are informed about “Special conditions of safe use” or any other limitations.
* Responsible - with help of the Product Compliance team – for annual check of the validity of all documents relating to Ex products considering any changes to standards, regulations and any other External specifications. Annual check should be part of his/her task list/plan.
* Be responsible for Exemptions (Exemptions for parts that take the product outside the design as defined as Ex critical in technical documentation is not allowed).
* Take action in case of non-conformity (including right to stop production).

Each production site management shall define the Local Ex Authorized Person(s) and his/her substitute (e.g. in GMH - Quality Engineer of the production line).

The Local Ex Authorized Person is responsible for effective coordination of the manufacturing process related to Ex products including:

* Externally provided products, services (e.g. quality of subcontracted parts, calibration).
* Non-conformity related tasks including right to stop production.
* Contact with 3rd party in regards of External Ex audits.

The Ex Authorized Person(s) shall participate in the annual Management Review.

Appointments shall be documented and shall contain responsibilities and authority it is recommended to document it in Job description.

## Competences

All person having impact on compliance of Ex products must be trained and competent. The training shall be registered.

# Requirements

All documents and quality records worked out in order to fulfill the requirements in this Group Standard must be controlled and archived so they can easily be found again.

### Technical documents (Technical Construction File)

A number of documents related to the product and system certification shall be included in the Technical Construction File. These include:

* Product and system certificates and subsequent information (e.g. as regards modifications, audit results, etc.).
* The technical documentation that has formed the basis of the type test and is enclosed with the Ex certificate. These documents typically could be:
* An ordinary description of the product type design. (In many cases, it is covered by the instruction/operation manual (further info about instruction in ANNEX 1)).
* Design and manufacturing drawings, drafts of components, sub-assemblies, circuits, etc. (e.g. Schedule drawing).
* Ignition Hazard Assessment (IHA) in case of non-electrical hazards identified.
* The necessary descriptions and Explanations to understand the above-mentioned drawings and drafts and the functioning of the product results from design calculations and Examinations, etc.
* The results of design calculations and Examinations, etc.
* Test reports.
* A list of the standards mentioned in Article 5 of the Directive (ATEX), or Test Report (IECEx), and which completely or partially are applied. Furthermore, descriptions of the solutions, which have been chosen with a view to fulfill the essential requirements where the standards mentioned in the above have not been applied.

*Detailed requirements of Technical Construction File are described in GI 402A0008-03 CE-Marking Requirements for the Technical Construction File.*

### Changes of Technical documents:

Technical documents used in the approval of the product represents the current design. The implementation of a modification have to be implemented as soon as possible (within 1 month). In case the implementation is expected to take longer, the approval should be requested on the way to cover the the old and the new desing as well.

### Manufacturer’s documents:

These are the documents which are not required of the product or system certifying authority when it handles the approval of the product or the system, but which are necessary to make Grundfos capable of ensuring the accordance between the product’s Ex certificate and the product which is actually produced and marketed. These could be:

* Related drawings
* Data sheets
* Quality documented information (e.g., Control Plan/Instruction Test/Measurement reports, Calibration reports)
* Responsibilities and authorities for Ex relevant role assignment
* Training records
* Design and development changes
* Manufacturing traceability records
* Contract review
* Sub-contractor evaluation
* Customer order and delivery data (including Serial number if available)
* External Audit reports (e.g., QAN/QAR)

Manufacturer’s documents shall be defined based on Technical Documents. Each document must be controlled and safely stored. Our basic repository is SAP, but other solutions can be acceptable.

Departments creating and controlling Ex related documents must describe how these are controlled and ensure that information in the Manufacturer’s documents is in accordance with the Technical documents.

An Ex related document must not be changed without prior acceptance by the Ex Authorized Person according to "Responsibility and authority" outlined in Section 3.1.

If the Manufacturer’s documents or Technical documents are passed on to companies outside the Grundfos Group (e.g. suppliers), these must be passed in an understandable way. In case of doubt, they must be followed by adequate information.

### Quality documents and records archive

Ex related quality documents and records must be filed and controlled by Grundfos 10 years after products have been delivered or the production has stopped. Documentation shall be able to demonstrate that an Ex product has been produced in accordance with its Ex certificate.

**Operation**

## Design and development

### Technical documentation:

Schedule drawings are describing the type of protection and include all of the Ex relevant information and in most cases are approved by the 3rd party. Schedule drawing stamp should be implemented on these drawings.

Drawings which form the basis for the products’ 3rd party Ex certificate cannot be modified unless otherwise permitted by the issuer of the certificate.

Related drawings are prepared for manufacturing Ex critical parts and all parameters defined in connected Technical documentation (e.g. Schedule drawing) should be marked with .

The relation between "Schedule drawings" and "Related drawings" must be clearly described.

If a drawing is part of the basis for several products’ Ex certificates, procedures must be established to ensure that additions are evaluated, approved and implemented at the same time for all products.

Ex critical parameter markings on design drawings should be prepared according “GS318A0001 Technical documents/drawing -Classification of requirements”.

The components forming the base of the protection types should be defined as “significant part”.

Part/component with critical parameters are not always defined as significant part (e.g. Screws of flameproof enclosure are Ex critical but not significant). Ex Authorized Person define it based on how critical the part is to the protection type.

Significant parts of Ex products should be traceable based on serial number or batch number. Designer shall define the Significant parts of product and it shall be marked on drawings (e.g. Mark the batch number place).

**Special requirements based on type of protection:**

**Ex d** – Flameproof enclosure

All parameter that form the flame path of “Ex d” protection type must be marked with [D]. Follow “GS318A0001 Technical documents/drawing -Classification of requirements”. 100% documented measurement method is preferred.

Parts of the enclosure which are forming the flame paths are Significant parts.

Blind holes in the flameproof enclosure shall not compromise the remaining wall thickness. In case a risk of thin wall due to a hole, the hole depth shall be marked with [D].

## Purchasing

### Outsourcing

Parts may be outsourced. However, the responsibility for the final Ex certified products’ compliance with the requirements stated in the Ex certificate must not be passed on to the supplier.

### Supplier evaluation

For all suppliers (providers) – internal as well as External – of Ex relevant parts, supplier evaluations must be carried out by Supplier Quality to verify that each supplier is able to comply with the requirements specified for the production process.

Compliance can be evaluated by one of the following methods:

1. Supplier’s Ex quality management system is assessed by an accredited body (e.g. QAR, QAN).

The quality management system certificate is prepared based on the appropriate standard (e.g. ISO 80079-34) and with acceptable scope (specific protection type production accepted).

1. Documented site assessment (Audit) to ensure all relevant controls are available and effective.
2. Incoming quality inspection.

100% or sample base check on the Ex parameter to verify a standard part.

The supplier’s ability to provide conforming products shall be evaluated periodically and this period should be less than a year.

When deciding what type of verification is required for the particular purchased process, product or service, it shall be considered:

* The competence of External provider
* How critical the supplied part/process/service is to the Type of Protection
* Is it possible to check the provided Ex parameter later?

In case it is not possible to do the inspection later, a) or b) should be implemented.

For suppliers who demonstrate full capability of producing and verifying the required product, no further internal verification is required if a Declaration of Conformity is supplied for each batch or product. GF402A0051-01 supplier Declaration of Conformity form is or similar is prefered to be used.

For evaluation of Ex Significant parts, suppliers shall be evaluated with a) or b) as a minimum. Regarding parameters marked with [D] 100% documented checking is preferred. If the verification is done by the supplier, the product shall be supplied with a Declaration of Conformity.

The evaluation related documentation (e.g. QAR, QAN) should be stored together with all other supplier related documentation.

### Determination of critical components

When purchasing parts for Ex certified products, the Ex Authorized Person is responsible for defining the parts and parameters which are Ex critical.

### Site assessment (Audit) of suppliers

*(In cases where the supplier evaluation is based on audit)*

When entering an agreement with a supplier concerning delivery of Ex marked parts, the agreement must ensure that relevant parts of the supplier’s quality system are allowed to be audited by Grundfos.

Supplier Quality must evaluate the suppliers from Ex point of view.

The supplier evaluation and its result must be registered.

The following must be part of the supplier evaluation:

* How critical is the part – is it included in the type of protection?
* The degree of difficulty of parts, process or services.
* Has the supplier outsourced some of the parts, processes, or services to a sub supplier?

The supplier evaluation must be carried out in one of the following ways:

Documented objective evidence that the supplier can provide suitable products could be:

* Ex quality management certificate issued by accredited body.
* A documented evaluation with objective proof demonstrating that the supplier is capable of delivering parts, processes or services in accordance with specified requirements.
* A supplier audit that verifies and documents that the necessary procedures are documented and working efficiently.

The supplier evaluation can be left out for the Ex critical parts if test and final inspection are performed at an Ex audited Grundfos production site.

Suppliers of Ex critical parts where the production quality cannot be verified later, e.g. encapsulated electrical circuits, must be audited when initiating the collaboration and regularly hereafter. These audit results must be registered.

Suppliers who have not delivered Ex critical parts for a year must be re-evaluated as a new supplier before placing an order. However, if a 100% incoming inspection is carried out for these parts, it is unnecessary to re-evaluate.

All suppliers of Ex critical parts must be evaluated at least once a year.

### Purchase information

The purchase order for Ex component(s) must contain the specification according to which the part(s) will be produced and tested, by listing drawing number, control instructions, assembly instructions, control plans, material specifications, etc. with version number (e.g. ECM).

In regard to Ex Critical parts that cannot be verified later, e.g. encapsulated electrical circuits, the purchase order must specify the requirements to produce and test the parts (E.g. Reference to the drawing associate with ECM).

Methods must be determined to ensure that the documents referred to in a purchase order remain traceable.

### Receipt of goods and incoming inspection

For each Ex critical part, the Extent of the incoming inspection must be decided so that the inspection proves the component is in accordance with the specifications stated in the product’s Ex certificate.

The Extent must be decided with respect to the type of protection, the character of the part, the type of supplier, the result of the supplier evaluation, etc.

Where it has been decided to pass on the control or the test of the Ex critical part to the supplier, the parts must be sent with a Declaration of Conformity confirming that the control is carried out according to the specified requirements.

If a supplier has been evaluated and it has been documented by objective evidence that the supplier can produce the parts according to specified requirements, no further incoming inspection is necessary as long as each part or batch is supplied with a Declaration of Conformity.

Where the product’s Ex certificate requires a routine test or inspection of parts, these must be carried out on each and every part. If it has been decided to let the supplier carry out these tests, the test must be specified in the purchase order and the parts must be delivered with a Declaration of Conformity.

Ex critical parts that cannot be verified later, e.g. encapsulated electrical circuits must be delivered with a Declaration of Conformity.

Where verification of a purchased product relates to the material (metals, alloys, non-metallic parts, resins and similar), a specific analysis certificate or documentation of compliance shall be supplied.

In case of metals: material certificate is acceptable.

In case of non-metallic materials: evidence of no change of recipe is required (e.g. in confirmation from supplier). The material package shall be marked with the identifier of the material and the batch (e.g. Expiration date is also be acceptable).

Parts that must be supplied with a Declaration of Conformity must not be released before this declaration has been received by Grundfos.

Declarations of Conformity, material certificates, etc., must be filed and controlled, so, they may be easily found again.

In case of components which have their own Ex related Type Test Certificate, the Certificate should be stored in SAP (set pdf Document Type) linked to the component.

If a test or inspection demands special skills or knowledge, these must be documented and registered.

This applies to both the persons who carry out the tests/controls at the supplier premises and the persons who carry out the test in connection with the incoming inspection at Grundfos.

In case of purchased parts with their own Ex certificate, only identification checking is need. The identification can be checked on incoming inspection or in production.

In questionable/not regulated situation, the ISO 80079-34 standard should be followed.

## Production

The production shall provide procedures, production equipment, working environments and inspection testing facilities to be able to produce the Ex product according technical documentation.

### Modification of production processes

In case of modification of a production processes of Ex critical parts or Ex certified products, the modification must be evaluated to secure continued compliance with the requirements of the Ex certificate.

### Traceability

All Ex products and their significant parts must be marked with a serial number or a batch code. Significant parts should be defined in the technical documentation. Relevant production and verification documentation of significant parts should be traced back based on product serial number for 10 years as minimum.

In case the significant parts/component are handled by sub-supplier(s), the information about Ex critical parameters should traceable back to the forming or verification point e.g. material certificate of casted component should be able to find based in the serial number of final products.

### Labeling of parts – product

All Ex related significant parts must be labeled with serial number or batch code, and this number/code must be kept until the product in which the components are placed has been finally assembled.

All Ex critical products must be labeled with serial numbers so that they can be identified during the entire production line and after they have been installed at the end-user.

For each produced product with serial number, the entered parts’ batch codes or serial numbers must be registered.

### Process monitoring

Where processes can influence the Ex critical measures of the product, and where it cannot be verified later, e.g. humidity and temperature during the molding process, the process parameters must be measured and registered.

### Test and inspection

For products where the Ex certificate and the “technical documents” demand routine test, these tests must be carried out on each and every product. Sampling tests are not allowed.

Where it is possible, the product must not be applied with a type plate before final test and inspection have been carried out with a satisfactory result.

### Measuring equipment

All measuring equipment used in connection with inspection and control of Ex critical parts or Ex certified products must be calibrated against standards with traceability to accredited calibration laboratories.

### Quality records

Quality records related to production must be adequate and sufficient enough to demonstrate conformity of the product.

### Non-conforming or potentially dangerous products

If it is found that products not in conformance with the Ex certificate have been delivered, the Ex Authorized Person must estimate the Extent of the consequences and ensure that the necessary containment, corrective and preventive actions are started.

If such non-conforming products, on the basis of risk analysis and their Ex certificate, have been assessed to be potentially unsafe for the users, the Ex Authorized Person must ensure that the customers are informed in writing about the recommended action to be taken, and that the Notified Body for the quality system is also informed in writing.

If it is impossible to identify the end-users of such potentially unsafe products (e.g. if a product is sold through a distributor), Grundfos representative must inform about the recommended action(s) to be taken in appropriate publications.

For such potentially unsafe products which have been delivered outside the Grundfos Group, the producing factory or the Local Ex Authorized Persons must keep registrations of the below information for 10 years:

* Serial number or identification of the delivered product.
* The customer who received the product.
* A description of the action taken to inform the customer and the system certifying authority in cases where the non-conforming products are considered to be potentially unsafe.
* A description of the containment, corrective and preventive actions which have been implemented.

### Exemptions

Ex critical characteristics of components should be prepared always according technical documentation. Exemptions are not allowed.

## Distribution and sales

### Contract review

In connection with order review and the associated order confirmation, it must clearly appear which type of Ex product the customer wants, and the labeling of the product.

Orders for EX approved products must be registered and filed. Furthermore, order review shall ensure that the customer requirement is within the specifications stated in the product’s Ex certificate.

The order confirmation must as a minimum describe:

* The type of Ex product and its labeling, e.g. ATEX/IECEx description (Ex II 2 G Ex c d IIB T3, T4 Gb), or FM listing (Class 1 Division 1 Groups C and D T3C)
* Additional Ex marking (e.g. not including alcohols (methanol) or aliphatic hydrocarbons (hexane))
* Ambient temperature (Ta = -20°C to +40°C)

In case of internet sales, if all relevant data is available to the customer, the contract review is not mandatory.

### Products/components delivered by the customer

If it is possible for a customer to deliver products/components that shall be part of an Ex certified product, it must be ensured during the order review that the customer delivered products are Ex certified.

### Instruction/Operation manual

All information required for using the product in hazardous area in safe way (e.g. special conditions for safe use) should be provided to the customer (further info see ANNEX 1).

### Traceability

To ensure traceability of Ex products, each serial number must be registered together with the order number at the latest when the product is shipped from the factory.

It must always be possible to identify the countries in which Ex products have been sold.

## Performance evaluation

### Internal Audit

Internal audit should be performed in relation to all Ex relevant products (Category 2 and 3 as well).

An Ex audit must be carried out on a regular basis to assess if all elements of the ISO 80079-34 and/or the FM “Quality Assurance guidelines” have been fulfilled, and thus if the quality system covering the Ex certified products is sufficient.

This internal audit must be carried out as a conformity audit and with an interval of maximum 14 months.

All non-conformities must be reported in the QEHS audit database.

### Management review

Quality Management activities covering Ex products must be evaluated regularly with an interval of maximum 14 months.

Top Management shall chair the review and the Ex Authorized Person(s) should participate on it.

The Management review shall assess the effectiveness of the quality management system covering the Ex certified products including internal and External audit results.

Information from Notified Bodies for both product and system, as well as the Ex audit results, must form part of the evaluation.

# Definitions

**Ex (certified, marked) product:**

Products intended for use in hazardous locations. Explosion proof products.

**Ex certificate:**

The certificate issued by a Notified Body when the product has been approved.

Ex certificate can be e.g. the EU type Examination certificate for ATEX, the IECEx Test Report/Certificate or FM issued certificate based on USA or Canada HazLoc (Hazardous Location) standard.

**Ex critical parts:**

Parts with Ex critical parameters. Parts cover raw materials, components, sub-assemblies and finished products used in other products.

**Ex critical parameters:**

Parameters defined in Technical documentation and most cases controlled by 3rd party. Critical to keep them to be sure Ex standards requirements are followed.

**Significant parts:**

Parts with high importance in regards type of protection. Traceability is these parts are mandatory.

**Technical Construction File**:

A document package demonstrates that the product meets the requirements of the applicable guidelines

**Ex Authorized Person:**

Person appointed to handle Ex relevant questions, tasks.

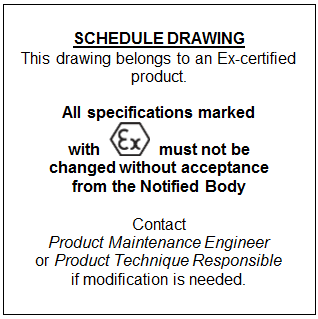
More details in 3.1Responsibility and authority

**Schedule drawing:**

Description in 4.1.1 Technical documentation part of this document.

Drawing referred to in the Ex certificate or test report.

**All schedule drawings be marked with the label below or similar:**

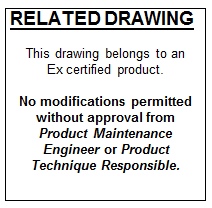


**Related drawing:**

Description in 4.1.1 Technical documentation part of this document.

Drawing not referred to in the Ex certificate or test report but used, for Example, for detailed manufacture of component parts.

**All related drawings must be marked with the label below or similar:**



**DoC, Declaration of Conformity from supplier :**

A declaration which comes with the parts and by which the supplier declares that the parts are produced according to the specifications that Grundfos has stated.

The declaration shall minimum contain the following:

* Unique identification of DoC
* Name and address of the supplier who is issuing the Declaration of Conformity.
* Identification of parts, processes, or services (i.e. name, type, and model number, and/or other relevant supporting information).
* The batch code or serial number of the supplied parts. If more than one batch is supplied, there shall be a declaration for each batch.  (Expiration date can also be acceptable in case of chemical material).
* A list of the documents which specify how the production parts are manufactured and controlled.
* Purchase order number.
* Batch size.
* The statement of conformity with critical parameters in the following format: We (issuer name) to declare that the information provided in this “External providers declaration of conformity” is accurate and confirm that the processes/products and services supplied by (issuer name) comply in all respects with the Purchase order requirements.
* Statement about production/service was not subcontracted to External provider without agreement with Grundfos.
* Date and place of issue of the declaration.
* The signature, name and function of the authorized person(s) acting on behalf of the supplier.
* Any limitation on the validity (if need)

*See "ISO/IEC 17050-1 and ISO/IEC 17050-2" requirements for the EC declaration of conformity for further reference.*

GF402A0051-01 supplier Declaration of Conformity firm is following the above mentioned requirements.

**QAN QAR, Quality Assurance Notification/Report:**

Certificate of development, production, etc., quality system based on 3rd party audit.

# Records

|  |  |  |  |
| --- | --- | --- | --- |
| Type of record | Where | How long | Responsible |
| N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A |

# References

|  |  |
| --- | --- |
| Document Number | Document Title |
| ATEX directive (2014/34/EU) | Equipment and protective systems intended for use in potentially Explosive atmospheres. |
| ISO 80079-34 | Explosive atmospheres – Part 34: Application of quality management systems for Ex Product manufacture |
| ISO 9001 | Quality management systems. Requirements. |
| ISO/IEC 17050-1 | Conformity assessment – Supplier-s declaration of conformity – Part 1: General requirements. |
| ISO/IEC 17050-2 | Conformity assessment – Supplier-s declaration of conformity – Part 2: Supporting documentation. |
| GS318A0001 | Technical documents/drawing -Classification of requirements |
| GS402A0069  GI402A0008-03 | Product Approvals  CE-Marking Requirements for the Technical File |
| GF402A0051-01 | Supplier Declaration of Conformity |

**ANNEX 1**

**Overview of minimum content of Ex relevant instruction (European market)**

General information (not Ex relevant)

* intended use,
* identification information (type key and some pictures),
* safety warnings (based on the Safety Risk Assessment),
* operating conditions if they are related to safety (the product will become a hazard if operated outside them, like: Ambient temperature, S1, Voltage),
* different installation instructions could be safety relevant (e.g. earthing) and
* DoC

On top of general information, it is also necessary to highlight the Ex relevant information.

Ex relevant information for the most common Ex d marked products based on ATEX/IECEx requirements (EN/IEC 60079-0 30.1, Annex D; EN/IEC 60079-1 21, Annex H; EN/IEC/ISO 80079-36 and EN/IEC/ISO 80079-37)

* Ex marking with standards (IECEx as well)
* Special condition of safe use based on certificates and/or internal test report (in relation X marking)
* Safe use information based in Ignition Hazard Assessment
* Recapitulation of the information with which the equipment is marked, Except for the serial number (we agreed with DEKRA: Nameplate OK)
* Electrical and pressure parameters
* Operating conditions if they are related to Ex safety (e.g. S3, maintenance of bearing, oil checking frequency)
* Ex safety relevant installation instructions (e.g.: Wiring diagram)
* Frequency converter usage info

For European and IECEx related sales, all Ex related information (special condition for safe use, etc.) must be on paper and on official language of the customer’s country, unless otherwise agreed with the customer.