D 03-EK-12

Version: 1

Date: 07/19

Revision: 07/24

**Scope of application:** This document applies within Freudenberg Performance

 Materials (FPM) and Freudenberg Filtration Technologies

 (FFT).

**Purpose:** Supplier self-disclosure for the creation of a new vendor or

 Resumption of dormant business relations (> 2 years)

**This document is only available online. Every printout is an unguided copy!**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **date** | **range** | **name** | **Signature** |
| **Created** | 28.05.2019 | FPM Service SE & Co. KG | Michael Heberger |  |
| **Released** | 03.06.2019 | FPM Service SE & Co. KG | Pierre Nyiondi |  |

# General Information

## Supplier contact information

|  |
| --- |
| Name of the company, type of company:Click or type here to enter text. |
| Address of the production site:Click or type here to enter text. |
| Contact person:Name: Click or type here to enter text.Function: Click or type here to enter text. |
| Telephone/Fax: Click or type here to enter text. |
| E-mail: Click or type here to enter text. |
| This document has been completed by:Name: Click or type here to enter text.Function: Click or type here to enter text. |

# Quality management system of the manufacturer

## Responsible persons

|  |
| --- |
| Quality assurance: Click or type here to enter text. |
| Production/Manufacturing:Click or type here to enter text. |
| Quality controlClick or type here to enter text. |
| Please attach a current organization chart. |

## Qualification requirements

|  |  |
| --- | --- |
| Does your company have a quality management system? | [ ]  yes [ ]  no |
| Are upstream suppliers of raw materials/substances/semi-finished products/components integrated into your quality management system? | [ ]  yes [ ]  no |
| Are you audited at regular intervals by official institutions? | [ ]  yes [ ]  no[ ]  n.a. |
| Which official institution are you audited by?<Name of authority> Click or type here to enter text. |
| Date of the last audit: Click or type here to enter text. |
| Is your company certified according to EN/ISO 9001? | [ ]  yes [ ]  no |
| Is your company certified according to EN/ISO 14001? | [ ]  yes [ ]  no |
| Has your company been audited by other companies in the last 5 years? | [ ]  yes [ ]  no |
| If so, by which?Click or type here to enter text. |

## Release and rejection

|  |
| --- |
| Is there a statement and logs about the release or rejection of  |
| Raw materials | [ ]  yes [ ]  no[ ]  n.a. |
| Intermediate products | [ ]  yes [ ]  no |
| End products | [ ]  yes [ ]  no |

## Risk Management and PQR

|  |  |
| --- | --- |
| Are risk analyses prepared? | [ ]  yes [ ]  no |
| Is there a procedure (process description) for risk management? | [ ]  yes [ ]  no |
| Is a Product Quality Review (PQR) carried out? | [ ]  yes [ ]  no |

## Change Management

|  |  |
| --- | --- |
| Are changes in the manufacturing process routinely communicated to the client? | [ ]  yes [ ]  no |
| Are changes in the product location/constructional changes routinely notified to the customer? | [ ]  yes [ ]  no |
| Will the customer be informed immediately of any changes to the product specification? | [ ]  yes [ ]  no |
| Who informs the client about changes?Click or type here to enter text. |

# Staff

|  |
| --- |
| Number of employees in |
| Quality assurance:  | Click or type here to enter text. |
| Production: | Click or type here to enter text. |
| Quality control: | Click or type here to enter text. |
| Do the employees have job instructions? | [ ]  yes [ ]  no |
| Is there a training program? | [ ]  yes [ ]  no |
| Is there a briefing for new employees? | [ ]  yes [ ]  no |
| Is there ongoing training for employees? | [ ]  yes [ ]  no |
| Will the efficiency of the training programme be reviewed? | [ ]  yes [ ]  no |
| Is there a success control? | [ ]  yes [ ]  no |
| Are there instructions on personnel and product hygiene? | [ ]  yes [ ]  no[ ]  n.a. |
| Are there any clothing regulations and are they being trained? | [ ]  yes [ ]  no[ ]  n.a. |
| Is the right way of changing clothes trained? | [ ]  yes [ ]  no[ ]  n.a. |
| Is there a health monitoring program? | [ ]  yes [ ]  no |
| Do you work in shifts? | [ ]  yes [ ]  no |
| If so, in how many shifts? Click or type here to enter text. |  |
| Is the staff supervised during all shifts? | [ ]  yes [ ]  no |

# Premises and equipment

|  |
| --- |
| There is a program, statements, and logs: |
| * Pest control
 | [ ]  yes [ ]  no |
| * Room qualification
 | [ ]  yes [ ]  no [ ]  n.a. |
| * Room cleaning/disinfection
 | [ ]  yes [ ]  no[ ]  n.a. |
| * Is there a hygiene plan?
 | [ ]  yes [ ]  no[ ]  n.a. |
| There is a program, statements, and logs: |
| * Qualification of systems/tools
 | [ ]  yes [ ]  no [ ]  n.a. |
| * Calibration of systems/tools
 | [ ]  yes [ ]  no[ ]  n.a. |
| * Handling of equipment/tools
 | [ ]  yes [ ]  no |
| * Test equipment monitoring
 | [ ]  yes [ ]  no[ ]  n.a. |
| * Cleaning of plants (also between two batches, between different products)
 | [ ]  yes [ ]  no[ ]  n.a. |
| * Service life (before and after cleaning)
 | [ ]  yes [ ]  no |
| * Status label
 | [ ]  yes [ ]  no |
| * Cleaning validation
 | [ ]  yes [ ]  no |
| In which areas are computer-aided systems used? | [ ]  in the production process [ ]  in the analytical field  |
| Are the computer-aided systems access protected? | [ ]  yes [ ]  no [ ]  n.a. |
| Are there written maintenance and operating procedures for the computerised systems? | [ ]  yes [ ]  no [ ]  n.a. |
| Are the computer-aided systems validated? | [ ]  yes [ ]  no [ ]  n.a. |
| Is there a long-term data backup including protection against failure? | [ ]  yes [ ]  no [ ]  n.a. |
| Do you use an electronic signature? | [ ]  yes [ ]  no [ ]  n.a. |

# Production (if available)

|  |  |
| --- | --- |
| How is the production carried out?  | [ ]  continuously[ ]  batchwise  |
| How is a batch defined?Click or type here to enter text. |
| What is the composition of the batch number?Click or type here to enter text. |
| Is there a complete batch traceability? | [ ]  yes [ ]  no |
| How is the batch size determined?Click or type here to enter text. |
| Usual batch size: ...Click or type here to enter text.Maximum batch size: ...Click or type here to enter text. |
| How is the date of manufacture defined?Click or type here to enter text. |

## Process validation

|  |  |
| --- | --- |
| Is there a program, instructions, and protocols for process validation? | [ ]  yes [ ]  no [ ]  n.a. |
| For which production steps are validation data available?Click or type here to enter text. |
| Is the validation periodically checked? | [ ]  yes [ ]  no [ ]  n.a. |

# Quality controls

## In-Process Controls / Integrated Process Control (IPC)

|  |  |
| --- | --- |
| Are IPC written instructions and protocols available? | [ ]  yes [ ]  no |
| Are IPC instructions approved by Quality Control? | [ ]  yes [ ]  no[ ]  n.a. |
| How is the IPC results checked? | [ ]  yes [ ]  no[ ]  n.a. |
| Have yield limits been defined? | [ ]  yes [ ]  no [ ]  n.a. |
| How are yields calculated and logged?Click or type here to enter text. |
| Describe the procedure in case of deviations.Click or type here to enter text. |

## Reserve samples

|  |  |
| --- | --- |
| Are samples retained for all batches? | [ ]  yes [ ]  no |
| How long are reserve samples stored?Click or type here to enter text. |  |

# Sales, Complaints, Product Defects and Recalls, Returns

|  |  |
| --- | --- |
| Are transport routes, transport dates and duration specified in writing? | [ ]  yes [ ]  no |
| If the goods are transported to the customer | [ ]  by the manufacturer [ ]  by commissioned forwarding agents |
| Are the forwarder and drivers trained? | [ ]  yes [ ]  no[ ]  n.a. |
| Is the forwarder qualified? | [ ]  yes [ ]  no[ ]  n.a. |
| Does the freight forwarder commission a subcontractor? | [ ]  yes [ ]  no |
| Is there a process description for dealing with |  |
| * Complaints, product defects including product counterfeiting, recalls
 | [ ]  yes [ ]  no |
| * Returns
 | [ ]  yes [ ]  no |