D 03-EK-12

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Date: 07/19

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**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)

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|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **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 control  Click 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 |