# Customer Quality Questionnaire

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# Customer Quality Questionnaire

## 1. Company details (Headquarter)

Supplier: **Klöckner Pentaplast Europe GmbH & Co. KG**

Address:

| postbox | postal |
|---|---|
| P.O. Box 1165 | Industriestraße 3-5 |
| 56401 Montabaur | 56412 Heiligenroth |

Telephone: +49.2602.915.0
Fax: +49.2602.915.297
E-mail: kpinfo@kpfilms.com
Web site: www.kpfilms.com

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Production Plant: **Klöckner Pentaplast GmbH**
**Site Montabaur**

Address:

| postbox | plant |
|---|---|
| P.O. Box 11 65 | Industriestraße 3-5 |
| 56401 Montabaur | 56412 Heiligenroth |

Telephone: +49.2602.915.0
Fax: +49.2602.915.297
E-mail: kpinfo@kpfilms.com
Establishment Year: 1965

**Facility Size**

Facility Site Size: 100.000 m²
Production Department Size: 32.000 m²
Warehouse capacity (finished goods): 4.200 tons

**What is the range of production and its % participation?**

| Segment | % share in sales | % share in quantity |
|---|---|---|
| **Pharma & Medical Device** | **53%** | **46%** |
| **Food** | **20%** | **27%** |
| **Technical application** | **27%** | **27%** |

**Capacity**

Total: 107.000 t
PVC: 88.000 t
PET: 15.000 t
Barrier: 4.000 t

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**Which shift system has the production?**
We run a five-shift system, which allows continuous operation 24 hours a day, 7 days a week (early, late and night shifts per day).

**Do you have a liability insurance? If so, what is the amount?**
Yes, we have a Public and Products Liability of 5.000.000 EUR.

**In which organisations/associations are you a member?**
- ERPA (European Rigid PVC-Film Association)
- EuPC (European Plastics Converters)
- Petcore Europe (PET trade association)
- Vinylplus (initiative of PVC)

## 1.1 Company Management

| ***Position*** | ***Name*** | ***Email*** |
|---|---|---|
| **Customer Service:** | Monika Luckas | monika.luckas@kpfilms.com |
| **Sales Representative:** | Francisco Marban | francisco.marban@kpfilms.com |
| **Quality Management:** | Michael Blech | michael.blech@kpfilms.com |
| **Quality Control:** | Michael Ehret | michael.ehret@kpfilms.com |
| **Environment Contact:** | Tobias Best | tobias.best@kpfilms.com |
| **Regulatory Affairs:** | Michaela Glomptner-Hofmann | michaela.glomptner-hof-mann@kpfilms.com |
| **Site Manager:** | Wolfram Krause | wolfram.krause@kpfilms.com |

| **Employees** | **Central kpE** | **Site Montabaur** |
|---|---|---|
| Total | 198 | 450 |
| Quality | 5 | 6 |
| Laboratory | 10 | 11 |
| SCM/Logistics | 20 | 35 |
| Marketing/Sales/Communicaions | 38 | / |
| Customer Service | 33 | / |
| Technical Support | 6 | / |
| Engineering/Maintenance | 3 | 43 |
| Production | / | 326 |
| **Group to which the company belongs (Parent Company)** | SVP (Strategic Value Partners) | |
| **Other production sites** (if several, please list with products) | See on our homepage: https://www.kpfilms.com/en/contact-us/_our-locations | |

| | |
|---|---|
| **Other storage locations / warehouse sites** | Hebgen Georg Spedition, Gewerbestraße 2, 56414 Oberahr |

## 2. Certifications

| *No.* | *Question* | *Response* |
|---|---|---|
| **A** | Which standards are certified acc. to the current versions? | - ISO 9001<br>- ISO 15378<br>- ISO 50001<br>- GMP / cGMP<br>- BRCGS Global Standard Packaging (including HACCP)<br>- ISO 14001<br>- Ecovadis<br>- Sedex<br>An overview is available on our homepage:<br>https://www.kpfilms.com |

## 3. Raw Materials

| *No.* | *Question* | *Yes* | *No* | *Comment* |
|---|---|---|---|---|
| **A** | Incoming raw material suppliers have been evaluated and found capable to meet all delivery and quality requirements? | ☒ | ☐ | |
| **B** | Certificate of analysis or adequate testing is in place for all raw materials? | ☒ | ☐ | |
| **C** | The quality of each incoming lot/batch is verified as acceptable before use? | ☒ | ☐ | |
| **D** | Are samples retained for each incoming lot/batch of raw materials? | ☒ | ☐ | |
| **E** | How long are samples from each incoming raw material lot/batch retained? | ☐ | ☐ | 3 months |
| **F** | Are incoming lots/batches quarantined / separated and released to prevent use before QC release? | ☒ | ☐ | |
| **G** | Are non-conforming raw materials clearly identified and segregated / quarantined? | ☒ | ☐ | |
| **H** | Are adequate storage areas on site for all raw materials? | ☒ | ☐ | silos, tanks and stocking areas |
| **I** | Are defined storage conditions maintained and controlled? | ☒ | ☐ | via maintenance and facility management |
| **J** | Are the storage conditions monitored? | ☐ | ☒ | n.a. not critical and recommendations only |
| **K** | Are there procedures to prevent deterioration, damage and contamination of raw materials? | ☒ | ☐ | |
| **L** | A system is in place to assure rotation of raw materials (e.g. FEFO)? | ☒ | ☐ | |

| | | | | |
|---|---|---|---|---|
| **M** | Written procedures are in place to prevent blending and usage of off-specification raw materials? | ☒ | ☐ | |

## 4. Manufacturing System

| *No.* | *Question* | *Yes* | *No* | *Comment* |
|---|---|---|---|---|
| **A** | Are procedures and measures in place to prevent cross-contamination of raw materials, products and packaging during the manufacturing process? | ☒ | ☐ | |
| **B** | Is the production equipment dedicated to specific products? | ☐ | ☒ | |
| **C** | Are there documented instructions/procedures for all inspections and process verifications? | ☒ | ☐ | |
| **D** | Are there cleaning procedures for production equipment and processes? | ☒ | ☐ | |
| **E** | Are manufacturing process records and IPC-data (in-process-controls) for each batch retained? | ☒ | ☐ | |
| **F** | Are production and quality control / quality assurance independent of each other? | ☒ | ☐ | |
| **G** | Quality results are determined or communicated back to production before proceeding to the next process? | ☒ | ☐ | |
| **H** | Are systems in place to identify out-of-control processes and document corrective actions? | ☒ | ☐ | |
| **I** | Is each raw material traceable through manufacturing to satisfy Recall accuracy requirements (Mock-up Recall)? | ☒ | ☐ | |
| **J** | Are tools and methods used during manufacturing to detect and separate known kinds of contamination? | ☒ | ☐ | |

## 5. Finished Goods

| *No.* | *Question* | *Yes* | *No* | *Comment* |
|---|---|---|---|---|
| **A** | How is your batch number defined? | ☐ | ☐ | The batch number is generated as an unique number in an ascending system in SAP. |
| **B** | How do you define a lot/batch and the size of a batch? | ☒ | ☐ | Customer order = process order = batch number; Size of a batch acc. to customer order. |
| **C** | Is acceptability of each finished lot/batch determined before delivery release? | ☒ | ☐ | |
| **D** | Is origin of any specific manufacturing locations identified on the labels? | ☒ | ☐ | |

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| | | | | |
|---|---|---|---|---|
| **E** | Are there written instructions for the testing and analyses? | ☒ | ☐ | |
| **F** | Are test and inspection reports stored? | ☒ | ☐ | |
| **G** | How long do you keep retain samples of batches? | ☐ | ☐ | Pharma: Samples are retained 7 years, batch records 10 years<br>Food & Tech: Samples are retained 2 years; batch records 7 years |
| **H** | Is release communicated in electronic writing and the product status is visible on the product label? | ☒ | ☐ | |
| **I** | Do you generate a Certificate of Analyses for every batch? | ☒ | ☐ | If requested |
| **J** | Certificate of analysis corresponds to all kp requirements? | ☒ | ☐ | |
| **K** | Are batches with varying physical / chemical properties blended to bring the final lot into specification? | ☐ | ☒ | |
| **L** | Are storage areas and procedures available and effective to prevent deterioration, damage and contamination of these finished goods? | ☒ | ☐ | |
| **M** | Are non-conforming goods clearly identified, labeled and segregated? | ☒ | ☐ | |
| **N** | Are non-conforming materials segregated to prevent inadvertent use and cross contamination with approved materials? | ☒ | ☐ | |
| **O** | Do you have a procedure for handling complaints? Are complaints periodically analyzed? | ☒ | ☐ | |
| **P** | Are written procedures in place to prevent shipping of products that doesn't meet the specifications? | ☒ | ☐ | |
| **Q** | Documented procedures exist to notify customers to whom defective product is delivered? | ☒ | ☐ | |
| **R** | A system is in place to bar code all finished goods? | ☒ | ☐ | |

## 6. Packaging and Storage

| ***No.*** | ***Question*** | ***Yes*** | ***No*** | ***Comment*** |
|---|---|---|---|---|
| **A** | Are packaging and shipping containers used to ship products designed and constructed to protect the product from alteration or damage? | ☒ | ☐ | |
| **B** | Are procedures in place to ensure that mix-ups, damage, deterioration, contamination or other adverse effects to product do not occur during handling? | ☒ | ☐ | |

| | | | | |
|---|---|---|---|---|
| **C** | Are procedures in place for the control of storage areas for product to prevent mix-ups, damage, deterioration, contamination or other adverse effects pending use or distribution? | ☒ | ☐ | |
| **D** | Are "age controlled" items identified as such and are there procedures in place to ensure their use (e.g., First-In-First-Expiry stock rotation) or removal prior to the expiration data? | ☒ | ☐ | |
| **E** | Are products in stock assessed at intervals in order to detect deterioration? | ☒ | ☐ | Routine checks in place |
| **F** | Have documented procedures been established for the verification, storage and maintenance of customer supplied product for incorporation into the supplies, or for related activities? | ☒ | ☐ | |

## 7. Quality

| ***No.*** | ***Question*** | ***Yes*** | ***No*** | ***Comment*** |
|---|---|---|---|---|
| **A** | Is there an effective, documented Quality management System in place according to ISO 9001? | ☒ | ☐ | |
| **B** | Are inspection facilities and laboratory equipment adequate for testing the quality of all products? | ☒ | ☐ | |
| **C** | Are calibration and preventive maintenance programs established for test equipment and records maintained? | ☒ | ☐ | |
| **D** | Procedures require regularly scheduled vendor audits? | ☒ | ☐ | |
| **E** | Is there a documented internal audit procedure and audit schedule? | ☒ | ☐ | |
| **F** | Are internal audits records, including findings, investigations, corrective actions and verifications retained? | ☒ | ☐ | |
| **G** | What is the procedure for responding to customer audit findings? | ☐ | ☐ | acc. to internal SOP, Respond time 30 days |
| **H** | What is the corrective and preventive action process for avoiding repetitive raw material problems? | ☐ | ☐ | established Improvements projects with supplier |
| **I** | A follow-up system is in place to determine if corrective action (for raw material) was effective? | ☒ | ☐ | |
| **J** | Products returned by customers are analyzed and appropriate corrective action is taken? | ☒ | ☐ | |

| | | | | |
|---|---|---|---|---|
| **K** | A verification process is in place to determine if corrective action is effective for all customer complaints? | ☒ | ☐ | |
| **L** | Do you communicate quality key performance indicators (KPI´s) and customer complaints internally? | ☒ | ☐ | |
| **M** | Which document management is in place? | ☐ | ☐ | Integrated Management System; Sharepoint system |

## 8. Change Control

| *No.* | *Question* | *Yes* | *No* | *Comment* |
|---|---|---|---|---|
| **A** | Do you have a written Change Control Procedure? | ☒ | ☐ | |
| **B** | Are changes assessed for potential quality impact? | ☒ | ☐ | |
| **C** | Are techniques used to assessed changes in quality (FMEA, etc)? | ☒ | ☐ | |
| **D** | Who is responsible for this evaluation? | ☐ | ☐ | Quality and assigned Change Control Team |
| **E** | Are changes approved prior to implementing the changes? | ☒ | ☐ | |
| **F** | Do you agree to notify Customer 6 months in advance for product changes involving formulation, production processes, production site or product specification? | ☒ | ☐ | |

## 9. Personnel

| *No.* | *Question* | *Yes* | *No* | *Comment* |
|---|---|---|---|---|
| **A** | Are there specific training requirements for each employee? | ☒ | ☐ | |
| **B** | Employee qualifications and training effectiveness is verified for each employee? | ☒ | ☐ | |
| **C** | Are there training procedures for every new employee? | ☒ | ☐ | |
| **D** | What annual training is required for all employees? | ☒ | ☐ | We provide face to face training and we use e-learning system. The training covers Hygiene, Quality, Safety and GMP aspects. |
| **E** | Are the testing of knowledge and training of employees documented? | ☒ | ☐ | |
| **F** | Is IT user access controlled? | ☒ | ☐ | |
| **G** | Software and data validations are perfomed at new installations and upgrades? | ☒ | ☐ | |

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## 10. Hygiene Management

| *No.* | *Question* | *Yes* | *No* | *Comment* |
|---|---|---|---|---|
| **A** | Is there a formal written hygiene policy/program? | ☒ | ☐ | |
| **B** | Is eating and smoking prohibited in the production and storage areas and locker rooms? | ☒ | ☐ | |
| **C** | Is there a program for control of pests and rodents? From whom is it controlled? | ☒ | ☐ | Astra Schädlingsbekämpfung GmbH |
| **D** | How often is the pest control service performed? | ☐ | ☐ | Every 4 weeks for the entire site, including warehouses for raw materials and finished goods. |
| **E** | Is the pest control monitored? | ☒ | ☐ | A monitoring is electronically available to see the history of the UV insect traps and bait stations. |
| **F** | Which measures have been taken for the protection from insects and other pests? | ☐ | ☐ | We have a pre-requisite program in place to avoid infestation. |
| **G** | Who carries out cleaning of machines, equipment, floors and walls? | ☒ | ☐ | Operator and external cleaning company |
| **H** | Are watches, jewellery (e.g. necklace rings, piercings, bracelets and ribbons), cosmetics and medications banned from production and product storage areas? | ☒ | ☐ | |
| **I** | Does the design of facilities and equipment minimize the risk of cross contamination, physical, chemical or microbiological? | ☒ | ☐ | |
| **J** | Before each production or packaging step, is there a line clearance performed and documented? | ☒ | ☐ | |
| **K** | Are clean work uniforms or covering over street clothes required in the production areas? | ☒ | ☐ | Each employee has to wear working clothes in the production which will be washed by an external company according to adequate timeline. |
| **L** | Do you produce more than one product simultaneously? If you do, which precautions do you take in order for not to cause any mix-up? | ☒ | ☐ | Clear identification by labelling, seperation of batches, Line clearance, use of dedicated equipment |
| **M** | Are procedures in place for line clearance? | ☒ | ☐ | |
| **N** | Is access to the manufacturing and storage areas restricted to authorized personnel? | ☒ | ☐ | |

## 11. Environmental Management

| *No.* | *Question* | *Yes* | *No* | *Comment* |
|---|---|---|---|---|
| **A** | Does the company have a formal, documented environmental system? | ☒ | ☐ | |

| | | | | |
|---|---|---|---|---|
| **B** | Does the company have an environmental policy? | ☒ | ☐ | |
| **C** | Are the products recycled and reused? | ☒ | ☐ | In agreement with the customer |
| **D** | Does your company use energy efficient equipment? | ☒ | ☐ | |
| **E** | Do you ensure that you meet all required local laws or regulations covering the environment? | ☒ | ☐ | |
| **F** | Have there been any complaints by neighbors or the community in general regarding airborne emissions or noxious odors? | ☐ | ☒ | |
| **G** | Are work & safety instructions in place in case of the accidental release of hazardous substances (task instructions, emergency plans, oil binders/absorbers, etc.) ? | ☒ | ☐ | |
| **H** | Fire protection, containment and evacuation plans are documented with routinely scheduled drills? | ☒ | ☐ | |

## 12. Regulatory affairs

| ***No.*** | ***Question*** | ***Yes*** | ***No*** | ***Comment*** |
|---|---|---|---|---|
| **A** | There is a procedure that guarantees the fulfillment of all European Food legislations and FDA legislations 21 CFR? | ☒ | ☐ | depends on film type |
| **B** | There is an information system to get all food and pharma regulatory news? | ☒ | ☐ | |
| **C** | Does your company have any representatives in food and pharma regulatory committees? | ☐ | ☒ | |
| **D** | Is your product registered within the Drug Master File No. 3764 of the Food and Drug Administration (FDA)? | ☐ | ☒ | depends on film type |
| **E** | Are your products compliant with all REACH (regulation 1906/2007/EC) requirements? | ☒ | ☐ | |
| **F** | Are your products labeled and packed acc. to CLP regulation 1272/2008/EC? | ☐ | ☐ | not applicable |

## 13. Site Security

| ***No.*** | ***Question*** | ***Yes*** | ***No*** | ***Comment*** |
|---|---|---|---|---|
| **A** | Do physical barriers prevent unauthorized entry to administrative, manufacturing, R&D, and warehouse areas? | ☒ | ☐ | |
| **B** | Are personal and business identifications of all visitors verified before entering the site? | ☒ | ☐ | |

| | | | | |
|---|---|---|---|---|
| **C** | Is the visitor's purpose, company host, and time of entry logged by the company representative? | ☒ | ☐ | |
| **D** | Is there a policy and a guideline to restrict visitors from observing competitive processes or competitors'products while onsite? | ☒ | ☐ | |
| **E** | Is there a clear responsibility assigned to computer system security (password control, user access, data backup, etc.)? | ☒ | ☐ | Annually checked by internal audit team |
| **F** | Are physical and/or logical control in place to restrict access to computerized system to authorized persons? | ☒ | ☐ | |
| **G** | Are changes to a computerized system including system configurations made in a controlled manner in accordance with a defined procedure? | ☒ | ☐ | |
| **H** | Are the computerized systems periodically evaluated to confirm that they remain in a valid state and are compliant with GMP? | ☒ | ☐ | |
| **I** | Can the system review and record the identity of the user? | ☒ | ☐ | |
| **J** | Is there a given program for the backup of the software and the data? | ☒ | ☐ | |

## 14. Identification and Traceability

| ***No.*** | ***Question*** | ***Yes*** | ***No*** | ***Comment*** |
|---|---|---|---|---|
| **B** | Is there a written procedure to ensure the traceability of raw materials/components? | ☒ | ☐ | |
| **C** | Is it possible to trace products back to specific lot or serial number? | ☒ | ☐ | |
| **D** | Do these procedures provide for unique identification of individual product or batches? | ☒ | ☐ | |
| **E** | Does the lot record include the date of manufacture, quantity manufactured, quantity shipped and lot number? | ☒ | ☐ | |

## 15. Declaration

We, Klöckner Pentaplast, declare that, to the best of our knowledge, all information provided within this questionnaire is complete and accurate.

| | |
|---|---|
| City & Date: | Heiligenroth, 08.09.2022 |
| Name & Position: | Michael Blech<br>Manager Quality kpM |
| Signature: |  <br>i.V.<br>Klöckner Pentaplast GmbH<br>Postfach 1165<br>56401 Montabaur |

## 16. Revision

| ***Version*** | ***Changes*** |
|---|---|
| 00/27.03.2017 | First edition |
| 01/23.05.2018 | Company management |
| 02/01.04.2019 | Annual update |
| 03/25.07.2019 | Update number of employees |
| 04/08.09.2020 | Company management |
| 05/05.10.2020 | General revision |
| 06/19.02.2021 | 3H/I/J/L; 4B and 7H |
| 07/02.11.2021 | 1.1 updated, 5K clarified, 6 D+E precised |
| 08/22.03.2022 | Annual update (Point 1) |