

# QUALITY PURCHASING GENERAL REQUIREMENTS

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**Document to be returned by the supplier with signature:**

Supplier / Subcontractor	Name	Function	Date	Signature

## **Preamble:**

The CLAYENS indication represents the group as well as the subsidiaries of the CLAYENS group, present and future. This document defines the Quality Purchasing General Requirements for the suppliers and subcontractors of CLAYENS. In this document, the supplier or subcontractor is named "supplier".

**Supplier:** company that delivers material, components or sub-assemblies.

**Subcontractor:** company that delivers value-added services on blank parts provided by CLAYENS

The quality purchasing general requirements shall be signed by the supplier in order to integrate the CLAYENS's list of suppliers. The latest updated version of this document is available in our internet site <https://www.clayens-np.com/les-fournisseurs>, such as the procedure 33 "Presentation of initial samples".

This commitment is valid between the two companies:

The company signatory to this document and THE CLAYENS GROUP, a simplified joint-stock company with capital of €31,903,850, having its headquarter at 10, Rue Jean Rostand – 69740 GENAS - France, registered in the Lyon Trade and Companies Register under number 500 212 188. Represented by Eric PISANI as CEO.

This commitment contract is valid for the entire life of the delivered products.

## **1 - CHOICE OF SUPPLIERS**

*"The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements". Extract from standard ISO 9001.*

### **1.1 Assessment and selection of suppliers**

New suppliers of CLAYENS Group are selected according priority to those being ISO 9001, IATF 16949, AQAP 2110, ISO13485, EN 9100 or EN9120... certified and for historical suppliers or imposed by customers no certified in minimum ISO 9001, it is requested to initiate the process of setting up a quality management system.

The pre-selection of a supplier is carried out by the Purchasing/Quality teams through a pre-assessment questionnaire, followed or not by a visit of the production plant, in order to evaluate his capabilities on technical and quality level to provide products with 0 defect.

A third-party certification shall be issued by a certification body bearing the accreditation mark of a recognized IAF MLA (International Accreditation Forum - Multilateral Recognition Arrangements) member and where the accreditation body's main scope includes management system certification to ISO/CEI 17021

Certification to IATF 16949 through third-party audits (valid third-party certification of the supplier to IATF 16949 by an IATF-recognized certification body)

### **1.2 Insurance policy**

The subscription to an insurance policy (liability insurance) is necessary within the framework of future developments with CLAYENS group.

The supplier will provide the subscription to one or several insurance contracts guaranteeing the financial consequences in relationship with the liability insurance, following the delivery of a defective product.

These insurance contracts must be in force during the time of partnership with CLAYENS group and take into consideration the failures that may occur during the product's life, even if the partnership with CLAYENS group has ended.

Moreover, the supplier must inform CLAYENS group of any change in these contracts.

### **1.3 Cost**

The price proposed by the supplier must favour competition and hence be consistent with the market. The supplier will show his ability to propose product and/or process improvements having a cost reduction effect.

### **1.4 Lead time respect**

The supplier will be evaluated on his lead time respect during the product's life.

A service rate calculation is made each month.

### **1.5 Innovation**

Both training level of the interlocutors proposed by the supplier and production methods used will be taken into account by CLAYENS group for the evaluation of the supplier's ability to propose innovative modifications.

### **1.6 Communication**

In order to facilitate his integration into working and improvement research meetings, it is important for the supplier to have working knowledge in French and/or English.

Therefore, all written or verbal information, 8D, initial samples files, etc. must be in French or English.

## **1.7 Invoicing**

In regards with our approach for dematerialised invoices, your invoices are expected in digital format -original PDF - (not scanned), instead of your original documents received by post.

Please find below the email addresses to use for sending original PDF and for all our subsidiaries:

. suppliers-invoices@clayens-np.com for CLAYENS  
. suppliers-invoices@siroco.fr for SIROCO  
. suppliers-invoices@aip-plast.fr for AIP  
. suppliers-invoices@np-savoie.com for NP SAVOIE  
. suppliers-invoices@np-sud.com for NP SUD  
. suppliers-invoices@np-nord.com for NP NORD  
. suppliers-invoices@np-vosges.com for NP VOSGES  
. suppliers-invoices@np-capelec.com for NP CAPELEC  
. suppliers-invoices@np-jura.com for NP JURA  
. suppliers-invoices@sicmo.com for SICMO  
. suppliers-invoices@np-simonin.com for NP SIMONIN  
. suppliers-invoices@np-tunisia.com for NP TUNISIA  
. suppliers-invoices@np-morocco.com for NP MOROCCO  
. suppliers-invoices@np-hungaria.com for NP HUNGARIA  
. suppliers-invoices@np-slovakia.com for NP SLOVAKIA  
. suppliers-invoices@np-germany.com for NP GERMANY  
. suppliers-invoices@np-polska.com for NP POLSKA  
suppliers-invoices-izernore@np-plastibell.com for NP PLASTIBELL  
suppliers-invoices@np-brion.com for NP BRION  
suppliers-invoices@pit-sas.com - PIT  
suppliers-invoices@np-piaseczno.com for NP PIASECZNO

The supplier can send in digital format (EDI, FACTUR-X, etc...), support is provided to answer your request at the following email address: suppliers-demat@clayens-np.com

Upon receipt, your email will be treated in order to validate the digital support.

Any invoice sent to another email address than those mentioned above, will not be processed or accounted.

## **1.8- Corporate Social Responsibility**

The third party will be assessed on its compliance with CSR criteria, CLAYENS incorporates into its supplier selection criteria their commitment to social responsibility.

# **2 - THE DELIVERY OF THE FIRST PARTS AND INITIAL SAMPLES:**

Field of application: parts on drawings, specific parts and subcontracting services as well.  
The standard parts and inserts delivered by the customer are not concerned by this paragraph.

## **2.1 Purchasing Specification**

A purchasing specification (DOC088) which summarizes the requirements of CLAYENS group is transmitted to the supplier in order to make sure that the supplier meet them.

This specification must be signed and returned by the supplier before the delivery of initial samples.

## **2.2 Prototypes**

A drawing and/or a specification is attached to the prototype order.  
A prototypes part's quality file may be requested, in the same way as for initial samples.

## **2.3 Presentation of initial samples**

A drawing and/or a specification is attached to the initial samples order.  
In reply to this order, the supplier must provide an initial sample file named the DAQP (Dossier d'Assurance Qualité Produit).  
Other designations: initial samples' file, DVI, FAI, containing all or part of the following elements (non-exhaustive list):

- The material safety data sheet
- The product data sheet (technical characteristics)
- REACH certificate and no Latex material
- ROHS certificate when applicable
- Certificate of material conformity
- Drawing used to produce the initial samples

- Synoptic flow chart
  - Process FMEA
  - Monitoring plan
  - Metrology report or control report related to the drawing and/or specification
  - Result of capability studies
  - Result of repeatability and reproducibility of the control means
  - Raw material certificate
  - Test report when required
  - P33 Appendix 3 "Part submission warrant"
- The exact content of this file is stated in the Purchasing specification (DOC088).

### **2.3.1 Health area specificity**

- Product risk management document: Product risk analysis of the component in the case of use for a DM (Health Device)
- Process risk management document: Process risk analysis of component production
- Production equipment qualification report IQ/QO/QP: Qualification document for production machines, packaging and CAZ (Controlled Atmosphere Zone) used in component's production

### **2.3.2 Specific to food sector**

For any product used in food products, a certificate of suitability for human consumption is required in line with regulatory changes and/or on request from CLAYES

#### **Application:**

- 1- Product/component suitable for food contact in accordance with the last regulatory amendment in force EC1935/2004
- 2- If the product/component is composed of plastic, it must be suitable for food contact, in accordance with the last regulatory amendment in force
- 3- The production of the product /component must comply with food manufacturing good practices in accordance with the last regulatory amendment in force EC2023/2006
- 4- Primary packaging (in contact with the product): must be suitable for food contact according to points 1, 2 and 3 above

Summary: The prerequisites require compliance with the following regulations (and their respective amendments) at CLAYENS and its suppliers:

- U.S. FDA - Code of Federal Regulations Title 21
- Regulation EC 1935/2004
- Regulation EU 10/2011 (1245/2020/CE)
- Regulation EC 2023/2006
- Suisse : Swiss Food and Commodity Ordinance SR 817.02, Chapter 3, Section 2
- China GB 4806.1-2016
- China Presidential Decree No. 21 (Food Safety Law of the People's Republic of China)
- South Korea : Standards and specifications for utensils, containers and packages (No. 2021-76)
- Japan : loi n°223 de 1947
- Singapore : Regulation of food under the Food Sales Act
- Taiwan : Food Safety Act
- Mercosur res. N°3/1992
- Mercosur res. N°20/2021
- France : French Decree 92/631
- Germany : BfR recommendation / LFGB 30-31
- Italy : Decreto 7 Febbraio 2019, n.30
- Phthalates Free
- Bisphenols free
- RoHS 3 (UE) 2015/863
- REACH 1907/2006/EC
- REACH-SVHC (last update in force)
- Food safe primary packaging : 1935/2004/CE, 2023/2006/CE
- Food safe primary packaging
- Plastic packaging : 1245/2020/CE (amendement de la 10/2011/CE)
- Recycled materials, regulation 2022/1616/EC

This list of regulations may change depending on our customer's needs. Certificates of food conformity may be requested from you on a regular basis, as the product you deliver to us must always comply with the last regulatory amendment in force mentioned above (or added later). In order to allow us to meet our client's response deadline, certificates must be sent to us within 10 business days.

### **Additional identification required:**

A "FOOD" identification must appear on the pallets received



### **Additional delivery conditions required:**

The packaging must comply with the article specification

Any pallet broken, non-compliant, dirty, with cartons crushed, torn, or misidentified will be refused

A check of conformity of the vehicles to the FOOD transport will be carried out at each delivery according to the following criteria:

- 1- Weather protection: no hole or notch
- 2- Trailer cleanliness: no particle deposition (iron, powder), no spillage of liquids, grease, etc.
- 3- No odours: no bad smell
- 4- Maintaining our product: by strap, handrail; or complete truck
- 5- Verify that product is not in contact with other products: no chemicals, tires, etc.
- 6- Orange food label on pallet: orange label if NOK to be applied before storage

For a courier package, check on package appearance only

Any deviation from one of these criteria will lead to either a refusal to unload or quarantine with the agreements of the quality and logistics managers. The supplier will be notified to find a solution.

#### ***2.4 Presentation of initial samples (procedure 33)***

The supplier will present the initial samples parts for free, together with the Quality Insurance Product file (PPAP) and identified according to the procedure P33.

If necessary, the supplier transmits assembly and use recommendations of the product.

#### ***2.5 Acceptance of initial samples (procedure 33)***

Following both submission of parts and Quality Insurance Product file (PPAP), a written agreement for acceptance is transmitted to the supplier, allowing mass production deliveries.

- The supplier does not deliver series parts without having received the written agreement for the acceptance of the initial samples, even if the parts were ordered and scheduled before.
- While waiting for the acceptance of the initial samples, the parts may be accepted under derogation, for a specified quantity.
- The supplier is committed not to modify the process in relation to the IS without prior authorisation of CLAYENS group (material grade, production plant change, suppliers, dimensions, aspect...).
- Any change will require a written information of the supplier and a new presentation of initial samples.

## **3 –MASS PRODUCTION DELIVERIES**

### ***3.1 Process control***

The processes used for the manufacture of mass production parts must be the same as those used for producing the initial samples and are in compliance with both production flow chart and monitoring/control plan.

For raw material, the last updated version of the Technical Data Sheet for the material must be systematically included to each delivery.

- In case of product or process non-compliance, the supplier must inform us immediately to possibly define a derogation.
- The supplier will keep the control recordings to our disposal, the control charts to respect the SPC frame and the material analysis certificates used for the manufacture of the product.

- Certificate of combustibility conformity have to be kept at disposal of CLAYENS each year. Warning, the tests must be done on at least 5 samples and the relevant standard must be imperatively specified (For example: D451333 for PSA – RSA, FMVSS302...).
- Should the capabilities of the process (Cpk) be lower than 1.33 on significant parameters, the supplier will make a 100 % check of the related products.
- Within the specific requirements mentioned in the purchasing specification (such as the respect of standards and particular specifications for raw material, special processes, suppliers designed or approved by the customer), the supplier guarantees that his own suppliers or sub-contractors are approved by our customer, so that the whole process is under control.
- The supplier must guarantee the assurance that people are sensitized:
  - Their contribution to the conformity of the product or service;
  - Their contribution to the security of the product;
  - The importance of ethical behaviour;
  - Their contribution to the prevention of the use of counterfeit parts.

### 3.2 Type and depth of the control of external services

Both requirements of the group CLAYENS and of Purchasing specification must be entirely passed on suppliers and subcontractors of our supplier. The supplier must identify and manage the risks associated to the tasks carried out by external contractors and must require from them to enforce the appropriate controls to their external suppliers of lower level as well.

This includes a quality management system and also a record-keeping, as well as the archiving lifetime and availability requirements. See paragraph 4.9 Traceability.

The use of parts or counterfeit components is prohibited.

## 4 – LOGISTICS

### 4.1 Acknowledgement of receipt

The supplier must verify the evolution of both forecasts and firm programs, and negotiate in case of capacities' overrun. Any delay or risk must be immediately reported.

Each order must be the subject of an acknowledgement of receipt of order, to be transmitted to the supply contact.

In case of delay, CLAYENS reserves the right to issue a non-conformity which may, if necessary, could lead to the cancellation of the order if an amicable agreement is not found.

### 4.2 Deliveries

All documents required must be supplied for each shipment or delivery.

CLAYENS group reserves the right to:

- Refuse the packaging that presents a risk for the operators' safety and the quality of goods.
- Return at supplier's expense any noncompliant shipment which does not meet the requirements defined in the Purchasing specification.

### 4.3 Handling unit

The handling units must be easy to catch by the handling machines and must correspond to the standards of the subsidiary of CLAYENS that is concerned. Contact the interlocutor of the subsidiary of CLAYENS in order to define them.

Should pallets be used, they have to be:

- Either covered in plastic film
- Or strapped. Plastic strapping will only be used if necessary.
- Or covered with a shrink-wrapped cover if necessary.

### 4.4 Packaging unit

Packaging units (boxes, bags ...) must be put palletized without exceeding the pallet.

Boxes have to be compliant with the standard Galia.

The maximum authorized weight per unit is **12 kg**, unless otherwise agreed by the CLAYENS subsidiary concerned.

- Are forbidden:**
- "Expanded polystyrene flakes" for wedging
  - Staples for the closing of boxes, bags.

### 4.5 Identification

Packaging and handling labels must comply with the standard Galia-Odette.

A delivery note must be attached to each delivery and:

- Be written in French and/or English
- Be presented in a plastic sleeve affixed on a visible package (it should never be inside the package).

Information to appear	Handling unit	Packaging unit	Delivery note
Name of the supplier	X	X	X
Code number of the supplier			X
Recipient name (CLAYENS subsidiary)			X
Art-No CLAYENS, its designation, its drawing number or reference with index	X	X	X

Quantity and unit used (kg, litre, piece, meter, etc.)	X	X	X
Batch number		X	X
Label number		X	
Date of production		X	
Hazardous product information, when appropriate	X	X	
Eventual shelf life date		X	X
Date of shipment			X
Delivery note number			X
Order number			X
Total gross weight			X
Total net weight			X
Number of packages or pallets (detailed checklist)			X
Incoterm			X
Name of the carrier			X

#### **4.6 Unloading**

Please get in touch with your contact at the CLAYENS subsidiary to know the unloading times.  
In order to avoid any incident, the driver:

- Must be present all the time during the unloading operations
- Will move his vehicle after the end of the operations only.

#### **4.7 Safety**

All hazardous products must be accompanied by a safety data sheet.  
Handling and packaging units must be identified accordingly.

#### **4.8 Evaluation of the logistics performance**

The supplier is committed to deliver all sites of the CLAYENS group according to the requested quantity, at the right time and together with the necessary documents.

A delivery is considered as compliant when:

- The received quantity is superior or equal to 90 % of the quantity ordered.
- The delivery is accepted within the time-slot [D-3; D+1] (either 3 days before or 1 day later), D being:
  - The requested date indicated in the order
  - Or the date confirmed in the acknowledgment of receipt of the order of the supplier, should this one be accepted.
- The delivery is identified according to the requirements and the packaging in good condition.

The service rate target is 100 % of compliant deliveries.

#### **4.9 Traceability**

The supplier will use a system of traceability allowing one, from labels or any other means, to identify the date and the place of manufacture, the batch of material used, the quality manufactured and the corresponding monitoring records.

The duration of archiving of the quality records linked to the products is 15 years and 50 years for products intended for the aeronautic sector, from the document's date. After archival periodicity, the confidential quality records will have to be destroyed to avoid all consultation by one not authorised customer.

Traceability elements must become available on request of CLAYENS and/or the end customer:

- Within the following 24 hours for standard products
- Within the following 6 hours for safety and/or regulation products (i.e. engine components for Aeronautics, automotive parts, etc.)

#### **4.10 Logistics treatment following a Quality non-compliance**

The production flow must not be disturbed by any product quality failure.

Should a non-compliance with an incidence on the flow be noticed in the plant, two specific cases may be considered:

- a) Return of the parts presumed non-compliant or dubious with return at the expense of the supplier.  
A delivery note is attached to the defective batch and will involve a credit note.  
The supplier must then deliver guaranteed compliant parts urgently, in order not to interrupt the flow.  
This solution is to be prioritized.
- b) In case of just-in-time and to avoid any production stop, the supplier will mandate people of a sorting company on the CLAYENS site or temporary workers acting on his behalf, in order to realize the sorting/rework operation.

Special transports may be necessary and will be at the expense of the supplier. In case of special transports, the supplier will send to the Purchasing Department of CLAYENS a listing of its extra costs, with monthly frequency.  
Appropriate measures may be considered with the supplier if the delay can't be absorbed.

## **5 – PERFORMANCE FOLLOW-UP**

All suppliers who deliver components or raw materials being part of the finished product's composition are evaluated on following criteria:

- Quality performance (number of quality incidents, demerit, ppm level)
- Logistics (service rate)
- Cost, through the purchase index

Performance on these three criteria determines who is awarded new business or the renewal of existing orders.

These evaluations are realized through internal monthly reports identifying the disruptions noted on the month concerned. Demerits are evaluated quarterly.

Within the CLAYENS group panel, some suppliers are defined as strategic suppliers.

Strategic suppliers are defined according to the following criteria:

- Turnover and volume (20% of suppliers representing 80% of Purchasing turnover)
- Technical know-how
- Expertise in a specific area
- Low turnover but high potential of development

Strategic suppliers are submitted to particular follow-up every six months.

The performance monitoring indicator of the strategic suppliers is calculated as follows:

### **Generality Mark/10: coefficient 1.5**

Financial: Takes into account the presence of insurance including liability and compliance of delivered products

Location: takes into account the international corruption perception index by country

NET CSR risk index: Index varying according to the requirements of CLAYENS on the purchasing family and with AFNOR mapping tool

### **Purchase Mark/10: coefficient 2.5**

Price according to the market /2.5

Service, reactivity /2.5

Ability to provide a technical and development support /2.5

Signed quality purchasing requirements (DOC250) /2.5

### **Quality system Mark/10: coefficient 1.5**

7/10 if supplier is ISO 9001 certified +

- IATF16949 if automotive application
- ISO 13485 if medical application
- EN 9100 or EN9120 if aeronautic application

5/10 if supplier is only ISO 9001 certified

3/10 if the supplier has no certification but is considered as able to meet our needs because of his specific know-how (patent, etc.).

- + 1 point if ISO 14001 certified
- + 1 point if ISO ISO 45001 certified
- + 1 point if ISO 50001 certified

### **Quality index Mark/10: coefficient 3**

According to the demerit points and ppm level.

Here are the demerit points:

55 points: non-conformity advice involving a return of parts or not, consequently to an incident at the final customer

40 points: non-conformity advice following production problems at CLAYENS

30 points: non-conformity advice following whether the reception

20 points: derogation with our own sorting

10 points: derogation without our own sorting

5 points: acceptance with observation (warning)

+ 15 points for each reminder to obtain corrective actions, in case of no reply from the supplier.

The quality index will be an average between the demerit mark and the ppm mark:

#### **Demerit mark**

(p = quantity of demerit points)

#### **ppm mark**

(ppm = ppm level)

10/10 if p = 0

9/10 if 5 ≤ p ≤ 15

8/10 if 20 ≤ p ≤ 50

7/10 if 55 ≤ p ≤ 80

6/10 if 85 ≤ p ≤ 95

5/10 if 100 ≤ p ≤ 120

4/10 if 125 ≤ p ≤ 145

3/10 if 150 ≤ p ≤ 170

2/10 if 175 ≤ o ≤ 195

1/10 if 200 ≤ p ≤ 220

0/10 if p ≥ 225

10/10 if ppm = 0

9/10 if 1 ≤ ppm ≤ 9

8/10 if 10 ≤ ppm ≤ 15

7/10 if 16 ≤ ppm ≤ 20

6/10 if 21 ≤ ppm ≤ 25

5/10 if 26 ≤ ppm ≤ 30

4/10 if 31 ≤ ppm ≤ 35

3/10 if 36 ≤ ppm ≤ 40

2/10 if 41 ≤ ppm ≤ 45

1/10 if 46 ≤ ppm ≤ 50

0/10 if ppm ≥ 51

### **Logistics mark/10: coefficient 1.5**



Percentage of the service rate extracted from the CAMM software (X3).

Service rate equivalent to 77% = 7.7/10

Service rate equivalent to 100% = 10/10

### **Global rating: realized every 6 months**

- If the indicator is not satisfying (final mark between 6/10 and 8/10):
  - An action plan from the supplier will be requested and an upgrading period will have to be defined together with the Purchasing Department.
- If the indicator is inferior to 6/10:
  - A risk assessment will be conducted within the Purchasing department (DOC580) to determine the conditions for the continuity of the relationship and to find solutions for continuous improvements with the supplier.

## **6 – SUPPLIER RESPONSIBILITY**

### **6.1 Non-conformity advice**

In the event of a complaint based on a proven non-conformity, a Non-Conformity Notice (ANC) will be issued, and must be the subject of an initial response within 24 hours and a detailed response within a maximum of 5 days, using an 8D format

The supplier is financially liable for all proven non-conformities (Quality or Logistics) observed on reception or when using parts which were purchased by CLAYENS or its customers.

Will be therefore invoiced:

- All costs linked to non-conformities of products received, to disruptions occurred (sorting upstream/downstream, internal/external, production stop, express shipping costs, chain stop, etc.).
- All other costs involved will be passed on to defaulting suppliers as well.

Fixed administrative fees are invoiced, should the demerit be equal or superior to 30 points, corresponding to the administrative treatment of an incident under the supplier's responsibility and being the subject of a non-conformity advice:

- 150 € (NC coming from a subsidiary of the group CLAYENS in Western Europe, United States of America and Mexico),
- 100 € (NC coming from a subsidiary in Eastern Europe),
- 50 € (NC coming from a subsidiary in the Maghreb).

The invoicing will only be set up when the responsibility of the supplier is completely established through the delivery of non-compliant products.

The supplier undertakes to deploy all serial production resources from the market allocation, regardless of the volumes and until the end of the product's life (with dedicated tools or not).

### **6.2 Confidentiality**

The supplier shall take all measures to avoid commercial or technical information relative to our orders and tenders to be disclosed to third parties, even fortuitously. Drawings and specifications must be kept in a safe place. The supplier undertakes to respect the bilateral confidentiality agreement CLAYENS, communicated under DOC428.

### **6.3 Audit / Access right**

With your prior agreement, CLAYENS or a quality auditor of the customer or authorities (Ex: DGA, DGAC ...) to conduct audits on products, processes or systems in its production premises to a convenient date agreed between both parties.

Depending on the results, CLAYENS reserves the right to cancel any market attribution, should the quality level not be reached.

### **6.4 Market stop**

Should a market stop be notified by our final customer, no obsolescence of finished products or raw materials is accepted for more than one month of consumption (average quantity smoothed on previous 12 months).

The supplier undertakes to store and maintain in a state of production the tools, including during after-sales service period.

### **6.5 Emergency Response Plan**

The supplier should:

- Methodically communicate and respond to any situation that could negatively impact CLAYENS operations. The supplier should implement all the necessary resources and guarantee the availability of a competent contact person to accompany the emergency situation with CLAYENS, reachable at all times.
- Implement a risk assessment process to identify critical supply chain areas that could impact the ability to meet CLAYENS Group requirements
- Identify and assess internal and external risks for all manufacturing processes and critical infrastructure equipment to maintain production performance and ensure supply chain continuity
- Define emergency plans taking into account risks and impacts for the customer

- Develop emergency plans to ensure continuity of supply in the event of any of the following situations: failure of key equipment, interruption due to products, processes or services provided by external providers, recurrent natural disasters, fires, interruptions in the delivery of certain "public" services (water, electricity, gas, etc.), labour shortages, infrastructure disruptions
- Include, as a supplement to the emergency plan, a notification process to inform the client and other interested parties of the extent and period of any situation affecting the client's operations
- Test periodically the effectiveness of emergency plans (for example, simulations based on what is most appropriate)
- Conduct periodic emergency plan reviews with a multi-disciplinary team including management and make necessary updates

Emergency plans must include provisions to validate that the manufactured product continues to meet the customer's specifications after production restart, following an emergency situation in which production was stopped without following the regular shutdown procedures.

## **7 – MANAGEMENT OF MODIFICATIONS**

The supplier's management system must include a change management procedure.

All modifications below are to be approved by CLAYENS before delivery. This applies to both modifications requested by the unit of the group CLAYENS and those proposed by suppliers.

The changes can be audited at the supplier.

### **7.1 System modification**

In case of major modification of its quality system (for example: loss or renewal of the ISO certification), the supplier must immediately contact CLAYENS. The supplier must therefore forward his updated certificates following renewal or inform of the evolution and indicate where they are to be found on the websites.

Example of major change (non-exhaustive list):

In the case of a change in governance or the organization chart impacting the customer contacts.

ERP software changes leading to a change in traceability management, customer delivery documentation.

The changes must serve as an internal registration coupled with a preliminary analysis taking into account the customer requirements.

### **7.2 Process modification**

In the case of a modification, even minor, of the initial process validated by the initial samples, approval must be requested (presentation of new initial samples). Any process changes validated via specifications/ PPAP must act as a risk analysis and a communication to the customer before the change.

Minor changes may correspond to (non-exhaustive list):

Retouched tooling, new product flow, new measuring equipment, new packaging method, etc.

CLAYENS reserves the right to refuse or accept the changes.

### **7.3 Product modification**

For any modification of the product, even minor, approval must be requested from the customer according to the requirements of CLAYENS Group.

Minor modifications are for example, any product characteristics that don't appear on the drawing or in the specification such as colour, finishing, etc.

Important modifications such as a new process, a new machine or a dimensional change, must require authorisation and systematically submit parts for validation accompanied by a control report, see paragraph above.

### **7.4 Logistics modification**

For any modification, even minor, of the logistics process (number of parts per container, delivery conditions, labelling and packaging, transporter, etc., non-exhaustive list) validated by initial samples, approval must be requested.

### **7.5 Notice of disclosure**

Prior to any change, a notice period must be respected. Unless a specific deadline is communicated via a specific specification and/ or a customer specification in the purchase data, the applicable notice period is set according to the table below:

The notice period starts once CLAYENS has acknowledged receipt of the request by return.

Type of change	Description	Notice period Excluding Medical/Health	AERO	Specific Medical/Health
Change impacting the product	Change in the characteristics of the product as defined in the specifications or/and in the purchasing data communicated at the beginning and/or in the series life of the product	3 months	3 months	12 months
	Change that in no way affects the performance of the product (example: change in packaging format)	1 month	1 month	3 months

Change impacting the manufacturing process	Change of equipment or modification of equipment that may affect the performance of the product or its physical characteristics (example: cleaning product of the component)	3 months	3 months	12 months
	Change of material in contact with the product (conveyor belt, gripping hand, primary packaging, etc. non-exhaustive list)	3 months	3 months	12 months
	Change of material without contact with the product (cleaning product of machine, mould, tools, etc. non-exhaustive list)	1 month		6 months
Change of manufacturing site	Transfer/Change of manufacturing site involving Quality Management System change, change of production equipment, change of manufacturing subcontractor	6 months	6 months	12 months
	Dropout/ loss of system certification/ accreditation/ special process qualification	15 days	15 days	15 days
	ERP change	3 months	6 months	6 months

In this table, the "product" refers to the component delivered by the supplier.

CLAYENS reserves the right to refuse the desired modification

## **8 – CONTINUOUS IMPROVEMENT**

Continuous improvement is the result of a philosophy of management and CLAYENS stays at disposal of his suppliers to share its experience in the field of continuous improvement. This philosophy is based on basic tools such as T.P.M, Kanban, the suggestion system, visual management and the 5S method.

In all sectors and exclusively in the health area, improvement can only be envisaged with the maintenance of safety and the guarantee of product conformity. In case of a change management must be applied to allow improvement.

### **8.1 Quality and costs**

Continuous improvement recommends the suppliers to be integrated into the project teams and encouraged to visit us and take part to working groups. It also implies that the suppliers propose improvements regarding quality and costs of products, and ask for contacts at all levels to report existing or possible problems.

In order to help the suppliers to strive for optimal performance, CLAYENS shall ask them for an improvement plan showing the evolution of key indicators such as:

- Number of returns from customer to plant
- Cost of scraps and reworks
- Overall Equipment Effectiveness
- Time scrolling
- Time of change in production
- Number of references
- Turnover per square meter
- Overall stock level
- Turnover per capita
- Number of improvement proposals per year and capita

### **8.2 Solid products**

The assemblies or sub-assemblies delivered by CLAYENS have to work in extreme conditions all around the world. To ensure this robustness, the components used for the manufacture of our products have also to be produced according to robust processes. A robust process is able to produce parts without any variation day after day, variation being the enemy of quality.

The best way, but not the only one, to reduce variation is to use the SPC (Statistical Process Control, what allows the continuous improvement of capabilities (Cpk). A stable value, for ex. 1.67, is not sufficient to guarantee the robustness of a process. Continuous improvement implies a permanent evolution of the capabilities of the processes.

## **9 – SAFETY AND REGULATIONS**

The supplier must have an organization allowing to ensure the respect of the constraints of both regulations and safety applicable in the country of manufacture and sales according to the products ordered and to the process of manufacturing used. Characteristics concerning safety and regulations are identified on our drawings with the symbol of the inverted triangle.



These characteristics require particular attention and are normally controlled by SPC follow-up. The inverted triangle must also be used to identify the workstations impacting the characteristics concerned and must appear on all documents such as control plans.

Other symbols, such as an asterisk, are frequently used to identify other special characteristics of both product and process. These characteristics also require particular attention, generally through SPC follow-up or Poka-Yoké. The interlocutor for the quality of external supplies may recommend the SPC follow-up; in this case, it may also be mentioned on the drawing or specification.

## **10 – SUSTAINABLE DEVELOPMENT & CSR CLAUSE**

CLAYENS recognises that responsibility and sustainability are key to its long term success. As a signatory to the United Nations Global Compact, CLAYENS is committed to promoting its core values in respect of human rights, labour, environmental and anti-corruption practices. CLAYENS is determined to ensure the highest standards of responsibility and sustainability throughout its operations including its supply chain. CLAYENS therefore expects its suppliers to meet the standards and requirements set out below.

### **10.1 Compliance with Laws**

Suppliers shall comply with all applicable laws and regulations of the countries in which operations are managed or services provided.

### **10.2 Human Rights**

Suppliers are expected to treat people with respect and dignity, encourage diversity, remain receptive to diverse opinions, promote equal opportunity for all, and foster an inclusive and ethical culture, in accordance with the relevant International Labour Organisation (ILO) conventions.

### **10.3 Child Labour**

Suppliers must ensure that illegal child labour is not used in the performance of work. The term "child" refers to any person under the minimum legal age for employment where the work is performed provided the legal age is consistent with the minimum working ages defined by the International Labour Organisation (ILO).

### **10.4 Human Trafficking, including Forced or Indentured Labour**

Suppliers must adhere to regulations prohibiting human trafficking, and comply with all applicable local laws in the country or countries in which they operate. Suppliers must refrain from violating the rights of others and address any adverse human rights impacts of their operations.

The supplier commits to keep at disposal the following elements to CLAYENS GROUP :

- A document with mention of his name or company name, complete address and company registration number (trade register, professional list or table).
- An affidavit stating payroll deductions dated as of less than 6 (six) months.
- A duly signed and dated affidavit stating compulsory tax payments and the deposit slip at the Business Formalities Centre, should he not be liable to be registered in the trade register.
- A duly signed and dated affidavit stating that:

a) Work will be done by regular employees according to the articles L.320, L.143-3 and R.143-2 of the Labour Code.

b) Potential foreign workers are or will be allowed to work in France

The supplier commits to obtain the same commitments from his potential suppliers and/or sub-contractors.

In case of change of the legal form of the company, these documents must also be provided.

The payment of the invoices will be made in favour of the supplier, subject to the providing of the above-mentioned documents.

### **10.5 Employment Practices**

#### **A Harassment**

Suppliers are expected to ensure that their employees are afforded an employment environment that is free from physical, psychological, and verbal harassment, or other abusive conduct.

#### **B Diversity – Non discrimination**

Clayens suppliers commit to comply with laws and regulations prohibiting any discrimination based on age, sex, religious beliefs, family situation, nationality, social or ethnic origin, state of health or disability, physical appearance, marital status, sexual orientation, political or philosophical opinions, trade union membership or other characteristics protected by

applicable law. In addition, suppliers and partners commit to prevent and sanction situations of physical, moral or psychological harassment.

Clayens suppliers recognizes and support the value of promoting visible and invisible diversity through women-owned businesses. Clayens supplier also recognizes and supports minority-owned businesses. We encourage our suppliers to implement programs that value minority inclusion to enhance their growth and prosperity.

## **C Wage and Benefits**

Suppliers must pay workers at least the minimum compensation required by local law and provide all legally mandated benefits. In addition to payment for regular hours of work, workers must be paid for overtime at such premium rate as is legally required or, in those countries where such laws do not exist, at least equal to their regular hourly payment rate. Deduction from wages as a disciplinary measure should not be permitted.

## **D Social Dialogue**

Suppliers are expected to respect the rights of workers to associate freely and communicate openly with management regarding working conditions without fear of harassment, intimidation, penalty, interference or reprisal. Suppliers are also expected to recognise and respect any rights of workers to exercise lawful rights of free association, including joining or not joining any association of their choosing.

## **10.6 Anti-Corruption**

### **A Anti-Corruption Laws**

Suppliers must comply with the anti-corruption laws, directives and regulations that govern operations in the countries in which they do business. Suppliers are required to refrain from offering or making any improper payments of money or anything of value to government officials, political parties, candidates for public office, or other persons. This includes a prohibition on facilitating payments intended to expedite or secure performance of a routine governmental action like obtaining a visa or customs clearance, even in locations where such activity may not violate local law. Personal safety payments are permitted where there is an imminent threat to health or safety. Suppliers are expected to exert reasonable due diligence to prevent and detect corruption in all business arrangements, including partnerships, joint ventures, offset agreements, and the hiring of intermediaries such as agents or consultants.

### **B Illegal Payments**

Suppliers must not offer any illegal payments to, or receive any illegal payments from, any customer, supplier, their agents, representatives or others. The receipt, payment, and/or promise of sums of money or anything of value, directly or indirectly, intended to exert undue influence or improper advantage is prohibited. This prohibition applies even in locations where such activity may not violate local law.

### **C Fraud and Deception**

Suppliers must not seek to gain any advantage of any kind by acting fraudulently, deceiving people or making false claims, or allow anyone else to do so. This includes defrauding or stealing from the company, a customer or any third party, and any kind of misappropriation of property.

### **D Competition and Antitrust**

Suppliers must not fix prices or rig bids with their competitors. They must not exchange current, recent, or future pricing information with competitors. Suppliers must refrain from participating in a cartel.

### **E Gifts/Business Courtesies**

Suppliers are expected to compete on the merits of their products and services. The exchange of business courtesies may not be used to gain an unfair competitive advantage. In any business relationship, suppliers must ensure that the offering or receipt of any gift or business courtesy is permitted by law and regulation, and that these exchanges do not violate the rules and standards of the recipient's organisation, and are consistent with reasonable marketplace customs and practices.

### **F Insider Trading**

Suppliers and their personnel must not use any material or non-publicly disclosed information obtained in the course of their business relationship with CLAYENS as the basis for trading or for enabling others to trade in the stock or securities of any company.

## **10.7 Conflict of interest**

Suppliers are expected to avoid all conflicts of interest or situations giving the appearance of a potential conflict of interest. Suppliers are expected to provide notification to all affected parties in the event that an actual or potential conflict of interest arises. This includes a conflict between the interests of CLAYENS and personal interests or those of close relatives, friends or associates.

## 10.8 Maintain Accurate Records

Suppliers are expected to create accurate records, and not alter any record entry to conceal or misrepresent the underlying transaction represented by it. All records, regardless of format, made or received as evidence of a business transaction must fully and accurately represent the transaction or event being documented. Records should be retained based on the applicable retention requirements.

## 10.9 Information Protection

### A Confidential / Proprietary Information

Suppliers shall properly handle sensitive information, including confidential, proprietary, and personal information. Information should not be used for any purpose (e.g. advertisement, publicity, and the like) other than the business purpose for which it was provided, unless there is prior authorisation from the owner of the information.

### B Intellectual Property

Suppliers must comply with all the applicable laws governing intellectual property rights assertions, including protection against disclosure, patents, copyrights, and trademarks.

### C Information Security

Suppliers must protect the confidential and proprietary information of others, including personal information, from unauthorised access, destruction, use, modification and disclosure, through appropriate physical and electronic security procedures. Suppliers must comply with applicable data privacy laws.

## 10.10 Environment, Health, and Safety

Suppliers are expected to establish an appropriate management system for Environment, Health and Safety. Suppliers are further expected to operate in a manner that actively manages risk, conserves natural resources and protects the environment in the communities within which they operate. Suppliers should protect the health, safety, and the welfare of their employees, contractors, visitors and others who may be affected by their activities. Finally, as stated in Section 1. "Compliance with Laws" of this document, suppliers shall comply with all applicable environmental, health and workplace safety laws and regulations.

CLAYENS encourages its suppliers to subscribe to an environmental, security and energy certification process, such as ISO14001, ISO45001, ISO50001 or at least have an equivalent policy.

CLAYENS requires its suppliers to develop technologies that respect the environment (control of pollutants and GHG emissions) and recycling.

Suppliers must implement actions aimed at controlling their carbon footprint as well as logistics strategies that limit environmental impacts (particularly in terms of storage, transport and transshipment).

## 10.11 Global Trade Compliance

### A Import

Suppliers must ensure that their business practices are in accordance with all applicable laws, directives and regulations governing the import of parts, components, and technical data.

### B Export

Suppliers must ensure that their business practices are in accordance with all applicable laws, directives and regulations governing the export of parts, components, and technical data. Suppliers shall provide truthful and accurate information and obtain export licences and/or consents where necessary.

### C Responsible Sourcing of Minerals

Suppliers must comply with applicable laws and regulations regarding conflict minerals which include tin, tungsten, tantalum and gold. Additionally, suppliers should establish a policy to reasonably assure that the tin, tungsten, tantalum and gold which may be contained in the products they manufacture do not directly or indirectly finance or benefit armed groups that are perpetrators of serious human rights abuses. Suppliers should exercise, as may be directed by law, due diligence on the source and chain of custody of these minerals and therefore at a minimum require the same from their next tier suppliers. Suppliers shall keep at disposal of CLAYENS the results of such diligence.

### D Counterfeit Parts

Suppliers are expected to develop, implement, and maintain effective methods and processes appropriate to their products to minimize the risk of introducing counterfeit parts and materials into deliverable products. In addition, suppliers shall provide notification to recipients of counterfeit product(s) when warranted, and exclude them from the delivered product.

## 10.12 Ethics Programme Expectations

### A Whistleblower Protection

Suppliers are expected to provide their employees with avenues for raising legal or ethical issues or concerns without fear of retaliation. Suppliers are also expected to take action to prevent, detect, and correct any retaliatory actions.

**B Consequences for violating the this document**

In the event that the expectations of this document are not met, the business relationship may be reviewed and corrective action pursued subject to the terms of the agreement, general/ specific conditions.

**C Ethics Policies**

Commensurate with the size and nature of their business, suppliers are expected to establish management systems to support compliance with laws and regulations, as well as the expectations expressed. Suppliers are encouraged to implement their own written code of conduct and to flow down their principles to the entities that furnish them with goods and services. CLAYENS expects its suppliers to maintain effective programmes to encourage their employees to make ethical, values driven choices in their business dealings - beyond compliance with laws, regulations and contract requirements.

**10.13 Corporate Social Responsibility clauses**

CLAYENS translates Corporate Social Responsibility into an organization's as the consideration of the impact of its own activities on its own business and on the environment. It goes with implementing transparent and ethical behavior with stakeholders and go through the following guidelines:

- Contribution to sustainable development, including the health and well-being of the company.
- Compliance with applicable regulatory and legal requirements and complies with international standards
- The integration of the whole organization, the implementation of the approach in its relations.
- Taking into account the requirements of stakeholders.

In compliance with its commitment to sustainable development, CLAYENS supports the following principles:

- Support and respect for the protection of human rights.
- Contribute to the monitoring of non-complicity of abuse in operations and contribute for the elimination of all forms of forced labor
- Participate and promote equality and the elimination of discrimination in employment
- Respect ethical business practices.
- Extend and communicate this responsibility to all responsible purchasing, ensuring that these principles are respected by their suppliers, partners, distributors and other third parties.

CLAYENS offers a self-assessment module to encourage its suppliers and subcontractors to know their positions on Corporate Social Responsibility concerns.

By entering into a contractual relationship with CLAYENS, each supplier and subcontractor commit to respect the principles of social responsibility and to collaborate with CLAYENS to implement, if necessary, an action plan and improvement of their performance in accordance with these principles.

In the event of non-compliance with the CSR principles mentioned in this clause, the CLAYENS Group reserves the right to terminate the contractual relationship with its suppliers.

Every supplier has the duty to escalate to the CLAYENS Purchasing Manager a report or any suspicion of breach of the commitments specified in this clause, including:

- Corruption
- Anti-competitive practices
- Conflicts of interest
- Inappropriate financial/banking/accounting practices
- Confidentiality
- intellectual property rights
- Child labour/forced labour/human rights
- Harassment/Discrimination
- Occupational Health, Safety and Health
- Environmental issues

**11 – ADDITIONAL REQUIREMENTS/ SUPPLIER COMPLEMENTS**

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