

PRELIMINARY QUESTIONNAIRE

FOR ESTIMATION OF PRODUCTION PLANT

PRELIMINARY INFORMATION

Name of producer

.....

Name of production place

.....

The number of production lines

.....

Name/type of product

.....

Application of product

.....

The plant experience in the production of the product:

- Before starting production
- A trial batch has been produced
- The product is manufactured in less than a year
- The product is manufactured in less than 3 year
- The product is manufactured for more than 3 years

.....
Place and date

.....
Signature

DETAILED INFORMATION**Quality system**

Does the plant have a documented quality management system in conformity with the standard PN-EN ISO-9001? YES NO

Does the plant have a documented factory production control system? YES NO

Does a FPC system is a part of quality management system? YES NO

Who is responsible for:

– quality management system:

– factory production control system:

Number of personnel connected with production of the product:

Are production workers responsible for control and testing?

– raw materials YES NO

– production processes YES NO

– final product YES NO

Are the activities of the above mentioned employees supervised by personnel unrelated to the production department? YES NO

Number of employees connected with the quality control of the product, but not production workers:

Who supervises the personnel controlling the quality of the product?

Are there internal audits in the factory production control areas? YES NO

Delivery control

What is the input/main material for the production of the product:

Main input/raw material for production is delivered:

- From your own plant
- From a plant that is part of the capital group
- From external suppliers

Is the quality of deliveries controlled? YES NO

Production

What are the main production stages (a diagram of the production process can be attached):

Production is realized:

for orders (customer is known prior to production) YES NO

to stock (customer is not known prior to production) YES NO

Records during the production concern:

the parameters of the production of product

product control during the production

identification of the products

Records from production are in form:

paper

electronic

Production records identify:

Single products

Production batch

Are any production processes outsourced to external companies? YES NO

It so, what are they?

If so, is it:

– are such processes controlled YES NO

– products after subcontracted processes are controlled YES NO

Are the methods of transport defined during production and storage? YES NO

How many working shifts is production carried out on? 1 2 3

Testing

Is there a documented test plan for the final product? YES NO

Does the test plan include all product properties/performances included in the technical specification? YES NO

If not, what tests are included in the final product test plan?

The tests are carried out:

- In your own laboratory
 In an external laboratory; what?:

Does the plant have measuring equipment?

YES NO

Is the measuring equipment used calibrated/checked?

YES NO

Calibration/checking of measuring equipment is carried out by:

- Own staff
 External not accredited laboratory
 External accredited laboratory

Non-conforming products

Is there a labelling system for non-compliant products ensuring their identification?

YES NO

Please give information on the quantity/ratio of non-conforming products*) found during last 12 months of production:

Please give complaints quantity/ratio*) during last 12 months:

*) – applies to products submitted for certification

Information about product

Information is placed:

- Directly on the product
 On the label attached to the product/set of products
 On the documents attached to product

Does the information about the product allow its full identification?

YES NO

Does the information about the product allow its traceability?

YES NO