CERT CERTIFICARE PRODUSE

SELF-ASSESSMENT QUESTIONNAIRE

(The filled in questionnaire is confidential)

The purpose of this questionnaire is to collect preliminary information concerning the certification applicant, as the producer / authorized representative of the producer, and his capability to provide the product subject to certification, according to the reference normative documents requirements.

The questionnaire form will be filled in by the certification applicant.

The questionnaire filled in and its attachments are **confidential document** and it is used by the RAR-OCP personnel in the activity of assessing the provider's capability to insure the continuous conformity of the manufacturing of the product subject to certification.

1 GENERAL INFORMATION

1.1 Name of the certification applicant: ……..……..
1.2 Address of the manufacture premise(s):……..…….
……..…….
1.3 Name of the General Manager:...…….
1.4 Organization size - total no. of employees: ……
1.5 Product identification:
1.5.1 Product denomination: ……...…….....……..
1.5.2 Type / variants / sizes:..... ……
1.6 Reference normative documents of the products (code, issue / revision no., date):
1.6.1 Company standard / techincal specification / national, foreign or international standard:
……
1.6.2 Regulatory requirements, legal requirements, etc: ……..……
……..……....
1.7 The product was subject to another certification application ? YES / NO
If YES: Certificate of conformity no. …..……., issued by ……
…….
1.7.1 **T**he product was subject to certification withdrawal / suspension ?YES / NO
If YES - for the following reasons: …….
…….…..
1.8 Is there a quality management system established, documented, implemented and maintained within the organization? YES / NO
If YES: Related to the requirements of: ……..……
1.9 Is the quality management certified ? YES / NO
If YES - Certification document no. …....……., issued by …….……..…….....….
……..
If NOT - Specify the status of the definition, documentation, implementation and maintaining of the technicques / methodes / instructions / procedures to fulfil the "Minimum requirements for the quality management system of the provider", code DG-01-13: ……..……
…….

2 ORGANIZATION AND RESOURCES

Ref.: subchapiter 5.1 - DG-01-13
subchapiter 5.5; 6 - SR EN ISO 9001:2008

2.1 Is there a **management reprezentative** appointed? YES / NO
If YES: his name:…….
2.2 The functions and their relationships, together with the authorities and reponsibilities for the established processes, are set out? YES / NO
If YES: Attach organizational chart

2.3 The reponsibilities and authorities are communicated at all relevant levels of the organization? YES / NO

If YES - Specify the manner of their communication:……

2.4 Personnel performing activities that affect product conformity is appropriately competent? YES/NO

2.5 The infrastructure necessary for product realization is ensured? YES / NO

2.6 The necessary working environment for product realization is ensured? YES / NO

3 DOCUMENTATION

Ref.: subchapiter 5.2 - DG-01-13
subchapiter 4.2 - SR EN ISO 9001:2008

3.1 The documentation concerning the intended product is established and available?YES / NO

3.2 The records required for product realization are established? YES / NO

3.3 Documents approval / re-approval manner is established? YES / NO

3.4 Which are the functions with responsibility and authority to control documents?

……
……

3.5 Which are the functions with responsibility and authority to control records?

……
……

4 SUPPLY

Ref.: subchapiter 5.3 - DG-01-13
subchapiter 7.4 - SR EN ISO 9001:2008

4.1 The requirements for the product supplied are defined? YES / NO

4.2 Is there a documented suppliers evaluation system? YES / NO

4.3 The methods for controling the supplied products are established? YES / NO

4.4 Indicate actions to be taken in case of non conformities of the supplied products

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5 PRODUCTION

Ref.: subchapiter 5.4 - DG-01-13
subchapiter 7.5 - SR EN ISO 9001:2008

5.1 Specify main production processes and their necessary steps to achieve the product:

……
……

Annex: technological flow chart, etc.

5.2 Special processes are used? YES / NO

If YES: indicate the special processes ……..

……

5.3 The special processes are validated? YES / NO

5.4 The information describing the characteristics of the product are available? YES / NO

5.5 Work instructions are available? YES / NO

5.6 The equipment used is appropriate? YES / NO

5.7 The measuring and monitoring equipments are available? YES / NO

5.8 The product characteristics are measured and monitored? YES / NO

5.9 Statistical control techniques are used? YES / NO

6 CONTROL OF MEASURING AND MONITORING EQUIPMENTS

Ref.: subchapiter 5.5 - DG-01-13
subchapiter 7.6 - SR EN ISO 9001:2008

6.1 A program of calibration and verification of measuring equipment, for their metrological confirmation is applied? YES / NO

If YES: specify metrological function, responsible for defining and implementing the program of calibration and verification program, as well as to keep under control the equipments: ……

6.2 Records regarding the results of metrological calibrations and verifications are kept? YES/NO

6.3 Specify how the status of calibration / verification is confirmed ……

7 CONTROL OF NONCONFORMING PRODUCT

Ref.: subchapiter 5.6 – DG-01-13
subchapiter 7 – SR EN ISO 9001:2008

7.1 The nonconforming product is identified and kept under control? YES / NO

7.2 The method for treatment of nonconforming product are established? YES / NO

7.3 The method for complaints treatment are established? YES /NO

7.4 Records on the nonconforming product / complaints and the actions adopted subsequently are maintained? YES / NO

8 CORRECTIVE ACTIONS

Ref.: subchapiter 5.7 – DG-01-13
subchapiter 8.3 – SR EN ISO 9001:2008

8.1 The function to decide which corrections / corrective actions applies to eliminate product nonconformities is established? YES ? NO

8.2 Action mode, so that corrective actions are appropriate to the effects of the appeared nonconformities, is established?

YES / NO

Annexes: ……. sheets

FILLED IN BY:

Name: ……...

Signature: …….

Date: …….