INITIAL QUESTIONNAIRE FOR FACTORY ASSESSMENT

(Annex to Application BFDA-CS-PR7.2-01-FM-01)

- This questionnaire should be completed and returned together with the application. It is intended to provide preliminary information relevant to the applicant and his/her capability to control the quality and continuous conformance of the product to the requirements of the relevant standard.
- This document will be used by inspector/auditor of BFDA-CS (Certification body) during preliminary visit to the factory as part of the initial inspection.
- Supplements may be included when it is necessary to expand any statement. A separate document should be completed for each factory involved, or variation between factories clearly indicated.
- The statements should relate to the facilities available at the date of completion of this form.
- The information given in this document will be treated in the strictest confidence.
- Please answer every question. A response 'Yes' or 'No' is accepted for most of the sections Negative responses do not disqualify the client's application. If the question is not applicable, mark N/A.
- Whenever supplements are attached as annexure, indicate clearly the annexure number and title.

A. PRELIMINARY INFORMATION ON APPLICATION

Information on the following subjects will furthermore facilitate the treatment of the application. Tick the appropriate response where the question so permits.

1. Indicate date when produce is available for evaluation:
2. Standard(s) for which you wish to become certified:
3. Do you have a copy of the standard according to which you request certification? Please tick. a) Hardcopy ☐ b) Access through internet ☐ c) No copy ☐
4. Scheme for which you wish to be certified:
5. Do you have a copy of the Scheme for which you wish to be certified? Please tick. a) Hardcopy ☐ b) Access through internet ☐ c) No copy ☐
6. Have the above mentioned product (in the application form) been tested to that standard? Please tick. a) Yes ☐ b) No ☐ If Yes, please attach report.

7. Type of sample. Please tick. a) Production ☐ b) Prototype ☐ If prototype, when is production schedule?
8. Urgency of application: Please tick a) Normal ☐ b) Urgent ☐

B. INFORMATION ON BASIC SYSTEM

Section 1 - Factory organization

Section 2 - Materials, components and services

Section 3 - Manufactures

Section 4 - Quality control and testing

Section 5 - Records and documentation

SECTION 1 - FACTORY ORGANISATION

1.1 Production/Pre-production Paperwork

Please give the following information on basic system.

1.1.1 Do you produce against order or for stock? Please tick. a) Order ☐ b) Stock ☐ c) Both ☐
1.1.2 Do you use a Work Order or Equivalent? Please tick. a) Yes ☐ b) No ☐
1.1.3 If yes, do you maintain different batch number for product produced under work order?
1.1.4 Do product and/ or container carry works order identification number? Please tick. a) Yes ☐ b) No ☐

1.1.5 If No, how does system allow for product to be isolated in cases of doubtful quality?
1.1.6 Please give any other relevant information on basic system.

1.2 Quality Control / Inspection Staff

Please give the following information on factory quality control structure of the Organization

1.2.1 Total Number of Staff in Quality Control Unit:
1.2.2 Head of Quality Assurance (Name and Designation):
1.2.3 Reporting to? (Name and Designation):
1.2.4 Is there a separate Quality Control and/or Inspection Department? Please tick. a) Yes ☐ b) No ☐
1.2.5 If Yes, indicate: 1.2.5.1 Name of Chief Inspector (Head), if different from 1.2.2: 1.2.5.2 Is inspection staff aware of the tests in the relevant standard(s)? Please tick. a) Yes ☐ b) No ☐
1.2.6 Does the quality control personnel inspect: 1.2.6.1 Materials? Please tick. a) Yes ☐ b) No ☐ 1.2.6.2 In-process operations? Please tick. a) Yes ☐ b) No ☐ 1.2.6.3 Final product? Please tick. a) Yes ☐ b) No ☐

1.2.7 If yes to any of the above, are these inspectors monitored by Quality Control staff? Please tick.

a) Yes ☐ b) No ☐

1.2.8 Are quality audit checks carried out? Please tick.

a) Yes ☐ b) No ☐

If Yes, by whom?

1.2.9 Please give any other additional information on staff working for Quality Control Unit.

SECTION 2 - MATERIALS, COMPONENTS AND SERVICES

2.1 Purchase specifications and materials quality assurance (if applicable). Please give information on the following or provide evidences as attachment.

- Detail of raw materials purchased
- Detail of packaging materials purchased
- Specifications used for raw materials and packaging materials
- Major suppliers involved
- Quality checks/tests conducted

2.2 Please give an overview of the quality assurance methods adopted on receipt of materials, components including actions taken on rejects.

SECTION 3 - MANUFACTURE

3.1 SYSTEM

Please attach the details of the various steps in manufacture. (A production processes and / or supplement in chart form showing stages may be advantageous).

3.2 EQUIPMENT MAINTENANCE SYSTEM

Describe the maintenance system in operation?

SECTION 4 - QUALITY CONTROL AND TESTING

4.1 QUALITY CONTROL SYSTEM

Please give details of the Quality Control System, including sampling plan followed, with particular reference to test in the relevant standard. (A quality control schedule or any supplement cross-reference in 3.1 in advantageous)

S.N	Name	Quality control check	Sampling plan	Method

4.2 LIST OF TEST EQUIPMENT / INSTRUMENT, GAUGES AND TOOLS FOR QUALITY CONTROL

S.N	**Name of the test equipment**	**Manufacturer's name**	**Calibration frequency**	**Calibration certificate number**

SECTION 5 - QUALITY RECORDS AND DOCUMENTATION

5.1 GENERAL

5.1.1 Please indicate the form of master specification in use (i.e drawing, product or part schedule,
or a reference sample etc). Please do also indicate the general records available.

5.1.2 Please indicate the system used to amend design or specification.

5.2 COMPLIANCE WITH SPECIFICATION

5.2.1 Please indicate the level of defectives found in the last three batches of production. If test in accordance with relevant standards have already been carried out, attach copies of summary of test result.

5.2.2 Please indicate the level of claims or complaints made under warranty and/or otherwise. Give this as a percentage of total output (Numbers as well).

5.2.3 Have independent test (apart from the in-house testing) been made on the product against the standard? Please tick.

a) Yes ☐ b) No ☐

5.2.4 If yes, by whom? Please also attach copies of test reports, if available.