	OPERATIONAL DOCUMENT	**CIG 423 Appendix 2**

Factory Inspection Report
Appendix 2
Additional Quality System Requirements
(QMS Appendix)

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Field Co

Reference number of the body carrying out the inspection:

Logo of the body carrying out the inspection

APPENDIX 2 TO OD CIG 423 FACTORY INSPECTION REPORT
Additional Quality System Requirements

(QMS Appendix)

GENERAL GUIDANCE

This Appendix is to be used if

- Compliance with EN ISO 9001 is required, and
- There is no certificate, issued by an accredited Body, to demonstrate that the Quality Management System complies with the requirements of EN ISO 9001.

***NOTE**:*

- *Instructions to the Inspector are shown in italics.*
- *The questions of this factory inspection report are based on the requirements given by the EN ISO 9001.*
- *This document is to be completed by Inspectors who are familiar with the requirements of EN ISO 9001.*
- *These requirements apply to quality management systems (QMS) for processes (including resources) related to certified product(s) only.*
- *QMS processes to be considered are: training, design changes, purchasing, incoming controls, storage, production, testing and management (policy and objective definition, internal audits, review and corrective action definition).*
- *For guidance, references to EN ISO 9001 paragraphs are provided.*
- *The report shall be completed even if there is no production at the time of the visit.*
- *For all 'NO' answers details shall be provided on the Inspector's Findings/Observation sheet (part 1).*
- *For all 'N/A' answers rationale shall be provided as to why the item is not applicable, unless it is obvious to be not relevant.*
- *Details should be given on Inspector's Information page.*
- *This report as well as objective evidence attached to this report shall be written at least in English.*

Compliance with these requirements does not imply full compliance to EN ISO 9001.

1 Factory registered name and factory location	
Factory registered name:	
Street and No.:	
Postal Code:	
City:	
Province:	
Country:	
GPS-coordinates *(optional)*:	☐ N: ☐ S: ☐ E: ☐ W:

Name of Inspector:	**Date of inspection:** *(YYYY-MM-DD)*

Reference number of the body carrying out the inspection:

Logo of the body carrying out the inspection

		YES	N/A	NO
2.1	**General Requirements** (in reference to **4.4.** as per EN ISO 9001): Has the organization established a QMS?	☐	☐	☐
2.2	**Quality Management system and processes** (in reference to **4.4.1.-4.4.2.** as per EN ISO 9001): Does the organization determine the sequence and interaction of processes needed, maintain and retain documented information to support the operation and interaction of its processes.	☐	☐	☐
	Does the QMS include (references to) procedures and instructions, documented information for processes?	☐	☐	☐
	Is the documented information up-to-date?	☐	☐	☐
2.3	**Document Control** (in reference to **7.5.** as per EN ISO 9001): Are all documents required by the QMS controlled?	☐	☐	☐
2.4	**Record control** (in reference to **7.5.** as per EN ISO 9001): Are records defined and kept for:	YES	N/A	NO
	- management review (2.9 as per OD CIG 423 Appendix 2) including action definitions	☐	☐	☐
	- supplier selection and evaluation (2.13 as per OD CIG 423 Appendix 2)	☐	☐	☐
	- incoming controls, in process controls, end tests (2.13 as per OD CIG 423 Appendix 2)	☐	☐	☐
	- customer complaints (2.12 as per OD CIG 423 Appendix 2)	☐	☐	☐
	- internal audits (2.15 as per OD CIG 423 Appendix 2)	☐	☐	☐
	- training (2.10 as per OD CIG 423 Appendix 2)	☐	☐	☐
	- maintenance (2.11 as per OD CIG 423 Appendix 2)	☐	☐	☐
	- calibration (2.11 as per OD CIG 423 Appendix 2)	☐	☐	☐
2.5	**Management commitment** (in reference to **5.1**. as per EN ISO 9001): Does management provide resources for the development of the QMS and QMS-processes?	☐	☐	☐
2.6	**Quality Policy** (in reference to **5.2.** as per EN ISO 9001): Has management defined and documented a quality policy?	☐	☐	☐
	Is the defined policy known by relevant employees? **(**in reference to **5.2.2. as per EN ISO 9001):**	☐	☐	☐
2.7	**Quality Objectives** (in reference to **6.2.** as per EN ISO 9001): Has management established measurable objectives?	☐	☐	☐
2.8	**Management representative** (in reference to **5.3.** as per EN ISO 9001): Is a management representative assigned with defined responsibilities and authorities for the processes, reporting on performance of QMS and promoting awareness of customer requirements and QMS-requirements?	☐	☐	☐

		YES	N/A	NO
2.9	**Management review** (in reference to **9.3.** as per EN ISO 9001): Has management reviewed the QMS in accordance with planned arrangements, including:			
	- process performance	☐	☐	☐
	- product quality	☐	☐	☐
	- customer complaints	☐	☐	☐
	- internal audit results	☐	☐	☐
	- corrective action results	☐	☐	☐
	- policy and objectives	☐	☐	☐
2.10	**Human resources** (in reference to **7.2.-7.3.** as per EN ISO 9001): Is the necessary competence of personnel including temporary personal determined and the necessary training identified and provided?	YES ☐	N/A ☐	NO ☐
2.11	**Infrastructure** (in reference to **7.1.3**. as per EN ISO 9001): Are installations, machines and instruments required for production and tests maintained in accordance with planned arrangements?	YES ☐	N/A ☐	NO ☐
2.12	**Customer related processes** (in reference to **8.2.1.** as per EN ISO 9001): Have arrangements to communicate with customers with regard to product information, enquiries and complaints been established?	YES ☐	N/A ☐	NO ☐
	Are customer requirements reviewed? **(**in reference to **4.2. as per** EN ISO 9001**):**	YES ☐	N/A ☐	NO ☐
2.13	**Purchasing process** (in reference to **8.4.** as per EN ISO 9001): Are suppliers selected and evaluated?	YES ☐	N/A ☐	NO ☐
2.14	**Control of production** (in reference to **8.5.** as per EN ISO 9001): Is the production carried out under controlled conditions, including the availability of work instructions, equipment and measuring devices, as applicable?	YES ☐	N/A ☐	NO ☐
	Is the product identified at all stages? **(**in reference to **8.5.2. as per** EN ISO 9001**):**	YES ☐	N/A ☐	NO ☐
2.15	**Monitoring and measurement** (in reference to **9.1.** as per EN ISO 9001): Are internal audits planned and executed? **(**in reference to **9.2. as per** EN ISO 9001**):**	YES ☐	N/A ☐	NO ☐
	Is it ensured that nonconforming products cannot be released? **(**in reference to **10.2. as per** EN ISO 9001**):**	YES ☐	N/A ☐	NO ☐