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| logo ETICS transparent | | **OPERATIONAL DOCUMENT** | **CIG 423**  **Appendix 2** |
|  | | | |
| **Factory Inspection Report Appendix 2** Additional Quality System Requirements  (QMS Appendix) | | | |
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| Approved by: | Full Members of CIG Inspection Scheme | | No. of pages: 3 |
| Date of issue: | April 2025 | |  |
| Supersedes: | OD CIG 023 Appendix 2 – December 2020 | |  |

APPENDIX 2 TO OD CIG 423 FACTORY INSPECTION REPORT

**Additional Quality System Requirements**

(QMS Appendix)

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| **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. |

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| 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)* |
|  | | | |

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| **2.1** | **General Requirements** (in reference to **4.4.** as per EN ISO 9001): Has the organization established a QMS? | YES | N/A | NO |
|  | | | | |
| **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. | YES | N/A | NO |
|  | | | | |
|  | Does the QMS include (references to) procedures and instructions, documented information for processes? | YES | N/A | NO |
|  | | | | |
|  | Is the documented information up-to-date? | YES | N/A | NO |
|  | | | | |
| **2.3** | **Document Control** (in reference to **7.5.** as per EN ISO 9001):  Are all documents required by the QMS controlled? | YES | N/A | NO |
|  | | | | |
| **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? | YES | N/A | NO |
|  | | | | |
| **2.6** | **Quality Policy** (in reference to **5.2.** as per EN ISO 9001):  Has management defined and documented a quality policy? | YES | N/A | NO |
|  | | | | |
|  | Is the defined policy known by relevant employees? **(**in reference to **5.2.2. as per EN ISO 9001):** | YES | N/A | NO |
|  | | | | |
| **2.7** | **Quality Objectives** (in reference to **6.2.** as per EN ISO 9001):  Has management established measurable objectives? | YES | N/A | NO |
|  | | | | |
| **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: | YES | N/A | NO |
|  | * 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 |
|  | | | | |