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| logo ETICS transparent | **OPERATIONAL DOCUMENT** | **CIG 023****Appendix 2** |
|  |
| **Factory Inspection ReportAppendix 2**Additional Quality System Requirementsfor the ENEC Agreement(ENEC Appendix) |
| WARNING: Appendix 2 to PD CIG 023 shall not contain any unauthorised modifications CHANGING the original meaning or the requirementsTHIS DOCUMENT IS ONLY VALID IF USED BY ENEC MEMBERS AND THEIR AUTHORISED AGENTS |
| Approved by: | Approved by ENEC members by correspondence | No. of pages: 1+3 |
| Date of issue: | December 2020 |  |
| Supersedes: | PD CIG 023 Appendix 2 – September 2014 | Page 1 of 4 |

APPENDIX 2 TO PD CIG 023 FACTORY INSPECTION REPORT

**Additional Quality System Requirements for the ENEC Agreement**

(ENEC Appendix)

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| **GENERAL GUIDANCE**This Appendix is to be used only if all of the following conditions apply to the Manufacturer:* ENEC certified products are manufactured, and
* Compliance with EN ISO 9001:2015 (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 or the certificate issued does not cover the production of the ENEC certified products.

***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 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 page.*
* *For all ‘N/A’ answers rationale shall be provided as to why the item is not applicable*
* *Details should be given on Inspector’s Information page.*

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

|  |  |
| --- | --- |
| 1 | Manufacturer's registered name and factory location |
| Manufacturer’s name: |       |
| Street and No.: |       |
| Postal Code: |       |
| City: |       |
| Province: |       |
| Country: |       |
| GPS-coordinates *(optional)*: |       |

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

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| --- | --- | --- | --- | --- |
| **2.1** | **General Requirements** (**4.4.** as per ISO 9001):Has the organisation established a QMS? | YES[ ]  | N/A[ ]  | NO[ ]  |
|       |
| **2.2** | **Quality Manual** (**4.4.1.- 4.4.2.** as per ISO 9001):Does the organisation have a quality manual (QM) with a description of the interaction of the QMS-processes? | YES[ ]  | N/A[ ]  | NO[ ]  |
|       |
|  | Does the QM include (references to) procedures and instructions for QMS-processes? | YES[ ]  | N/A[ ]  | NO[ ]  |
|       |
|  | Is the QM up-to-date? | YES[ ]  | N/A[ ]  | NO[ ]  |
|       |
| **2.3** | **Document Control** (**7.5.** as per ISO 9001):Are all documents required by the QMS controlled? | YES[ ]  | N/A[ ]  | NO[ ]  |
|       |
| **2.4** | **Record control** (**7.5.** as per ISO 9001):Are records defined and kept for: | YES | N/A | NO |
|  | * management review (2.9 as per CIG 023 Appendix 2) including action definitions
 | [ ]  | [ ]  | [ ]  |
|  | * supplier selection and evaluation (2.13 as per CIG 023 Appendix 2)
 | [ ]  | [ ]  | [ ]  |
|  | * incoming controls, in process controls, end tests (2.13 as per CIG 023 Appendix 2)
 | [ ]  | [ ]  | [ ]  |
|  | * customer complaints (2.12 as per CIG 023 Appendix 2)
 | [ ]  | [ ]  | [ ]  |
|  | * internal audits (2.15 as per CIG 023 Appendix 2)
 | [ ]  | [ ]  | [ ]  |
|  | * training (2.10 as per CIG 023 Appendix 2)
 | [ ]  | [ ]  | [ ]  |
|  | * maintenance (2.11 as per CIG 023 Appendix 2)
 | [ ]  | [ ]  | [ ]  |
|  | * calibration (2.11 as per CIG 023 Appendix 2)
 | [ ]  | [ ]  | [ ]  |
|       |
| **2.5** | **Management commitment** (**5.1**. as per ISO 9001):Does management provide resources for the development of the QMS and QMS-processes? | YES[ ]  | N/A[ ]  | NO[ ]  |
|       |
| **2.6** | **Quality Policy** (**5.2.** as per ISO 9001):Has management defined and documented a quality policy? | YES[ ]  | N/A[ ]  | NO[ ]  |
|       |
|  | Is the defined policy known by relevant employees? **(5.2.2. as per ISO 9001):** | YES[ ]  | N/A[ ]  | NO[ ]  |
|       |
| **2.7** | **Quality Objectives** (**6.2.** as per ISO 9001):Has management established measurable objectives? | YES[ ]  | N/A[ ]  | NO[ ]  |
|       |
| **2.8** | **Management representative** (**5.3.** as per 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** (**9.3.** as per 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** (**7.2.-7.3.** as per 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** (7.1.3. as per 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** (**8.2.1.** as per 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? **(4.2. as per ISO 9001):** | YES[ ]  | N/A[ ]  | NO[ ]  |
|       |
| **2.13** | **Purchasing process** (**8.4.** as per ISO 9001):Are suppliers selected and evaluated? | YES[ ]  | N/A[ ]  | NO[ ]  |
|       |
| **2.14** | **Control of production** (**8.5. – 7.1.5.** as per 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? **(8.5.2. as per ISO 9001):** | YES[ ]  | N/A[ ]  | NO[ ]  |
|       |
| **2.15** | **Monitoring and measurement** (**9.1.** as per ISO 9001):Are internal audits planned and executed? **(9.2. as per ISO 9001):** | YES[ ]  | N/A[ ]  | NO[ ]  |
|       |
|  | Is it ensured that nonconforming products cannot be released? **(10.2. as per ISO 9001):** | YES[ ]  | N/A[ ]  | NO[ ]  |
|       |