Guide to the Solar Keymark Factory Inspection Report

1 Introduction

This document serves as a guide line for the factory inspection and the related report within the Solar Keymark certification and is based on the current template for the Solar Keymark Factory Inspection Report (SKN_N0132R1), dated yyyy-mm-dd.
The main target groups are the inspectors performing the factory inspections. However this document can also help the manufacturer of solar thermal products to get prepared for the inspection.

Basic rules for the completion of the factory inspection report:
- All dates shall be displayed in the following format: yyyy-mm-dd.
- Do not leave any field without any filling but use appropriate input (e.g. ”-”, none, not relevant, etc.).

2 Layout

The layout of the factory inspection report uses a page header and a page footer. The page header needs to be completed with a unique Report No. of the factory inspection report and the date of the report (yyyy-mm-dd), see below.

Solar Keymark FACTORY INSPECTION REPORT	Report No.: XYZabc	Report date 2012-08-20	Page 2 (21)

The page footer leaves room to display name, address, etc. oOf the institution of the inspector.

3 General

Just before the section “0. General” starts the details regarding the company for which the report is issued shall be listed according to the following format:

Issued to:	**Company name which the report is issued to** Contact Person Email Tel.: Address Postal Code Town Country

Section “0. General” looks the following:

0. General

0.1	**Date of inspection**	**yyyy-mm-dd**
0.2	**Type of inspection**	☐ Follow-up ☐ Initial (pre-licence) ☐ Sample selection
0.3	**Report No. and date of last inspection**	**Nnn, yyyy-mm-dd**
0.4a	**Holder of the certificate/s** *(fill in company name and full address or make reference to “Issued to:” above)*	Name of manufacturer Street Postal code Town Country

0.5a	**Certificate No., Test report No., Date of test report**		**Product name**
	Cert No: **XX, Test report No XX, yyyy-mm-dd**		Solaris xy
	Cert No: **XX, Test report No XX, yyyy-mm-dd**		…
	Cert No: **XX, Test report No XX, yyyy-mm-dd**		…
0.4b	**Holder of the certificate/s (OEM/OBL)**	Name of manufacturer Street Postal code Town Country	
0.5b	**Certificate No., Test report No., Date of test report**		**Product name**
	Cert No: **XX, Test report No XX, yyyy-mm-dd**		Solaris xy
	Cert No: **XX, Test report No XX, yyyy-mm-dd**		…
	Cert No: **XX, Test report No XX, yyyy-mm-dd**		…
0.6	**Manufacturer's** registered name and factory location	Name of manufacturer Street Postal code Town Country	
0.7	**Names and positions** of persons seen in the factory	Name, Surname, Position …	
0.8	**Number of non-conformities** (also see 13)	Xx	

Ad 0.1 Date of inspection: Enter the date when the inspection was carried out. In case the inspection lasts longer than one day write e.g. 2012-08-20 to 2012-08-21.

Ad 0.2 Type of inspection: Tick weather it is an initial or follow-up inspection. In case samples are picked from stock or production line during the inspection tick sample selection as well.

Ad 0.3 Report No. and date of last inspection: Enter the Report No. and the date of the last inspection (only for follow-up inspections), e.g. SolMan2011, dated 2011-05-31.

Ad 0.4a Holder of the certificate: Enter the name of the holder of the certificate with all details if the holder is different to the company the report is issued to.

Ad 0.5a Certificate No., Test report No., date of test report, product name: Enter certificate no., test report no., date of test report and product name for all certified products produced at the inspected factory, e.g. Cert.No.: 011-7S9999 F, Test report No.: 12COL999, dated 2012-08-20, FPC 2099.
In case of a new product please indicate only the product name and make reference to sample selection.

Ad 0.4b Holder of the certificate: Enter the holder of the certificate with all details. In case of further certificate holders (OEM/OBL) add 0.4c, 0.4d, etc. to the list.

Ad 0.5b Certificate No., Test report No., date of test report, product name: Enter certificate no., test report no., date of test report, and product name for all certified products (OEM/OBL) produced at the inspected factory, e.g. Cert.No.: 011-7S9999 F, Test report No.: 12COL999, dated 2012-08-20, FPC 2099.
In case of a new product please indicate only the product name and make reference to sample selection.

In case of further certificate holders (OEM/OBL) add 0.5c, 0.5d, etc. to the list.

Ad 0.6 Manufacture´s registered name and factory location: Please enter the manufacture´s registered name and factory location where the inspection is carried out.

Ad 0.8 Names and positions: Please enter the names and positions of the relevant persons you talked to during the inspection, e.g. Bruno Boss, CEO and Dr. Peter Pan, quality manager.

Ad 0.9 Number of non-conformities: Enter the overall numbers of non-conformities found and documented during the inspection.

4 Quality system

Section “1. Quality system” looks the following:

1. Quality system

		yes	no
1.1	Does the manufacturer hold a certified quality management system that includes the products in question? *Certification number and expire date must be documented here.* *A copy of the current certificate shall be attached to this report.*	☐	☐
Certification No.			
Date of expiry:			
Remarks:			

Tick ”no” in case the manufacture does not hold a certified quality management system. In case he does hold a certified quality management system tick ”yes” and record the Certification No., the date of expiry and add a copy of the certificate to the factory inspection report. Use the field remarks in case you want to report about an upcoming ISO 9001 certification or other valuable information.

5 Production during visit

Section “2. Production during visit” looks the following:

2. Production during visit

		yes	no
2.1	Were the products included in the certification or aimed for certification, in production at the time of the visit? *If "Yes", identify product name and any Cert.-No. that appeared on them. If "No", make sure and confirm that similar products were manufactured at the time of the visit.*	☐	☐
Products in production:			
Remarks:			

Tick ”yes” if at least one of the certified products or the product for which certification is aimed for are under production during the inspection. In this case list the product names and certification no. (if any) of the products the production was witnessed.
Tick ”no” in case other products have been produced and list the product names and certification no. (if any) of the products the production was witnessed.
Use the field ”Remarks” for any additional relevant information.

6 Incoming goods

Section “3. Incoming goods” deals with all the materials, components, sub-assemblies and services coming from the supplier(s) of the manufacturer needed for the production of the product(s) subject to the factory inspection and is separated in 5 different (3.1 to 3.5) blocks. These blocks are the following:

		yes	partially	no
3.1	Does the manufacturer have an up to date part list/bill of materials (BOM) of the product(s) subject to the factory inspection?	☐	☐	☐
List of assessed documents:				
Remarks:				
Non-conformities:				

To ensure products of constant quality an up to date part list is essential. This part list summarizes all parts needed to build the product. The part list must include a date of revision in order to trace back changes during the next inspection. The part list must be filed by the inspector.
Tick ”yes” in case an up to date part list including the date of revision is available.
Tick ”partially” in case the part list is incomplete.
Tick ”no” in case no part list or only a very incomplete part list is available.

List the document numbers of the part lists and the current date of revision under ”List of assessed documents” and use ”Remarks” when necessary.

List non-conformities including deadlines for corresponding corrective actions if necessary.

Note: Solar Keymark certification can only be granted if yes is ticked. In all other cases the corresponding corrective actions need to be fulfilled before certification.

		yes	partially	no
3.2	Does the manufacturer have documented specifications for all these materials, components, sub-assemblies and services relevant to products subject to the factory inspection? *If yes, at least one case must be assessed and filed by the inspection body.*	☐	☐	☐
List of assessed documents:				
Remarks:				
Non-conformities:				

Exact specifications of material, components, sub-assemblies and services are needed to ensure that the product always looks and performs the same than the certified product.
Typical specifications are the thickness and the optical properties (absorptivity and emissivity) of the absorber sheet. The manufacturer should have complete specifications of all material, components, sub-assemblies and services needed to build the product. These specifications should be part of his quality management system. In case technical data sheets of suppliers are used as internal specification this has to be done referring to the date of revision of the data sheet.
At least one case of a key component, e.g. absorber, glass cover or heat pipe (collector) shall be assessed in detail by the inspector.
Tick ”yes” in case complete specifications are available.
Tick ”partially” in case the specifications are incomplete.

Tick ”no” in case the specifications are not available or very incomplete.

List the document numbers of the specifications and the current date of revision under ”List of assessed documents” and use ”Remarks” when necessary.

List non-conformities including deadlines for corresponding corrective actions if necessary.

Note: Solar Keymark certification can only be granted if yes is ticked. In all other cases the corresponding non-conformities need to be fulfilled before certification.

		yes	partially	no
3.3	Does the manufacturer ensure that the purchased products and/or subcontracted services are in conformity with the specified requirements?	☐	☐	☐
List of assessed documents:				
Remarks:				
Non-conformities:				

To ensure that the purchased material, components, sub-assemblies and services are in conformity with the specifications the manufacturer is obliged to check the incoming goods. The frequency of the checks must be documented within the quality management system and can be defined by the manufacturer, however it cannot be reduced to zero. To realize the incoming goods inspection different approaches are possible:

- In house measurements
- Third party measurements
- Audits at the supplier
- Any other reasonable means

At least the incoming goods inspection for the materials assessed under 3.2 shall be assessed in detail by the inspector.
Tick ”yes” in case all the specifications are checked on a regular basis.
Tick ”partially” in case the specifications are not checked completely.
Tick ”no” in case the checks of the specifications are not or performed only very limited.

List the documents assessed under ”List of assessed documents” and use ”Remarks” when necessary.

List non-conformities including deadlines for corresponding corrective actions if necessary.

		yes	partially	no
3.4	Is there a documented procedure covering the way to handle materials, components, subassemblies, services and end products which are found to deviate from the specification to such an extent that the conformity with the product is endangered?	☐	☐	☐
List of assessed documents:				
Remarks:				
Non-conformities:				

To ensure that non-conform materials, components, sub-assemblies, services and end products are not used a documented procedure needs to be part of the quality management system which describes how these parts are treated.
Tick ”yes” in case such a procedure is in place and used.
Tick ”partially” in case such a procedure is not implemented to a satisfactory extent.
Tick ”no” in case such a procedure is not in place.

List the documents assessed under ”List of assessed documents” and use ”Remarks” when necessary.

List non-conformities including deadlines for corresponding corrective actions if necessary.

		yes	partially	no
3.5	Are non-conforming products clearly identified and/or segregated to prevent any unauthorised use?	☐	☐	☐
List of assessed documents:				
Remarks:				
Non-conformities:				

To ensure that non-conforming materials, components, sub-assemblies and services are not used within the production they need to be clearly identified/marked or segregated from the production process.
Tick ”yes” in case the products are clearly marked and/or segregated from the production process.
Tick ”partially” in case this is not done to full extend.
Tick ”no” in case these products are not marked or segregated from the production process.

List the documents assessed under ”List of assessed documents” and use ”Remarks” when necessary.

List non-conformities including deadlines for corresponding corrective actions if necessary.

7 Production control and routine tests

Section “4. Production control and routine tests” is dealing with the controls and tests during the production process and is separated in 6 different (4.1 to 4.6) blocks. These blocks are the following:

		yes	partially	no
4.1	Is there a documented procedure describing the measurements and tests performed during the whole production process?	☐	☐	☐
List of assessed documents:				
Remarks:				
Non-conformities:				

Usually the production of solar thermal products goes along with different checks and tests until the product is completed. These checks and tests need to be documented within the quality management system. This can be done by a special document, a certain number of working instructions or any other applicable document. Depending on the size of the manufacturer and/or the complexity of the product more or less checks/tests are performed.

However at least a final check (product release) of the produced product is required to achieve the Solar Keymark certification.
Tick ”yes” in case a documented procedure is in place and used.
Tick ”no” in case no procedure is in place.
Tick ”partially” in case you find a situation between ”yes” and ”no”.

List the documents assessed under ”List of assessed documents” and use ”Remarks” when necessary.

List non-conformities including deadlines for corresponding corrective actions if necessary.

		yes	partially	no
4.2	Are the responsibilities for the tests conducted during production including the decision for the product release clearly documented?	☐	☐	☐
List of assessed documents:				
Remarks:				
Non-conformities:				

The responsibilities for the checks/tests carried out and the final product release must be clearly defined.

List the documents assessed under ”List of assessed documents” and use ”Remarks” when necessary.

List non-conformities including deadlines for corresponding corrective actions if necessary.

		yes	partially	no
4.3	Does the staff have ready available up-to-date documents, like as procedures, quality plans, inspection and test instructions, photographs, drawings or samples on all those parts that have an impact on the conformity of the finished products?	☐	☐	☐
List of assessed documents:				
Remarks:				
Non-conformities:				

Within the production up to date documents, like as procedures/work instructions, quality plans, inspection and test instructions, photographs, drawings or samples are needed.

Tick ”yes” in case the documents are available at the production.
Tick ”no” in case the documents are not available.
Tick ”partially” in case you find a situation between ”yes” and ”no”.

List the documents assessed under ”List of assessed documents” and use ”Remarks” when necessary.

List non-conformities including deadlines for corresponding corrective actions if necessary.

		yes	partially	no
4.4	Are there appropriate records about all the checks and tests done during the production available?	☐	☐	☐

List of assessed documents:	
Remarks:	
Non-conformities:	

All test/checks performed during production need to be recorded. Records can be completed and signed testing protocols or signed labels on the corresponding half product. In case no records are available the tests are considered as not performed.

Tick ”yes” in case the records are available.
Tick ”no” in case the records are not available.
Tick ”partially” in case you find a situation between ”yes” and ”no”.

List the documents assessed under ”List of assessed documents” and use ”Remarks” when necessary.

List non-conformities including deadlines for corresponding corrective actions if necessary.

		yes	partially	no
4.5	Is there a documented procedure describing how to handle non-conforming products and are they clearly identified and/or segregated to prevent any unauthorised use?	☐	☐	☐

List of assessed documents:	
Remarks:	
Non-conformity:	

To ensure that non-conforming products are treated correctly a documented procedure needs to be part of the quality management system which describes how this is done.
Tick ”yes” in case such a procedure is in place and used.
Tick ”partially” in case such a procedure is not implemented to a satisfactory extent.
Tick ”no” in case such a procedure is not in place.

List the documents assessed under ”List of assessed documents” and use ”Remarks” when necessary.

List non-conformities including deadlines for corresponding corrective actions if necessary.

		yes	partially	no
4.6	Are trends of test results monitored and reported to the production and management authorities?	☐	☐	☐

List of assessed documents:	
Remarks:	
Non-conformity:	

To improve the quality of the product and the production process the trends of the test results need to be monitored and reported to the production and the management authorities.

Tick ”yes” in case the trends of the test results are monitored and reported.
Tick ”no” in case the trends of the test results are not monitored and reported.
Tick ”partially” in case you find a situation between ”yes” and ”no”.

List the documents assessed under ”List of assessed documents” and use ”Remarks” when necessary.

List non-conformities including deadlines for corresponding corrective actions if necessary.

8 Calibration/check of measuring equipment

Section “5. Calibration/check of measuring equipment” deals with the measuring equipment used during the incoming goods inspection and production. Typical measuring equipment is e.g. caliber for length or thickness measurements, pressure gauges for leakage tests, spectrometer for the measurements of the optical properties of the absorber coating, etc.
Calibration is only needed if the measured value is relevant for the performance of the product, e.g. absorptance of absorber coating. For other measuring equipment e.g. pressure gauges for leakage test a check of the equipment is sufficient. The section is separated in 5 different (5.1 to 5.5) blocks. These blocks are the following:

		yes	partially	no
5.1	Is there a documented procedure describing how to handle measuring equipment including the responsibilities related?	☐	☐	☐
List of assessed documents:				
Remarks:				
Non-conformities:				

A documented procedure must be available describing the way measuring equipment is handled and the responsibility for the different tasks.
Tick ”yes” in case a documented procedure is available and all responsibilities are clearly defined.
Tick ”no” in case a documented procedure is not available.
Tick ”partially” in case you find a situation between ”yes” and ”no”.

List the documents assessed under ”List of assessed documents” and use ”Remarks” when necessary.

List non-conformities including deadlines for corresponding corrective actions if necessary.

		yes	partially	no
5.2	Is a list with all equipment used for measurements available?	☐	☐	☐
List of assessed documents:				
Remarks:				
Non-conformities:				

A list with all measuring equipment including the ID of the equipment, status of calibration, date of next calibration and location must be available.
Tick ”yes” in case the list is available and complete.

Tick ”no” in case the list is not available.
Tick ”partially” in case you find a situation between ”yes” and ”no”.

List the documents assessed under ”List of assessed documents” and use ”Remarks” when necessary.

List non-conformities including deadlines for corresponding corrective actions if necessary.

		yes	partially	no
5.3	Is the relevant measuring equipment calibrated/checked and marked with ID?	☐	☐	☐
List of assessed documents:				
Remarks:				
Non-conformities:				

All measuring equipment used must have an ID-tag on it if possible. In case this is not possible the equipment must be clearly identified by e.g. the serial no. and the list of measuring equipment (see 5.2).
Tick ”yes” in case the measuring equipment is clearly marked.
Tick ”no” in case the measuring equipment is not marked.
Tick ”partially” in case some are marked others are not marked.

List the documents assessed under ”List of assessed documents” and use ”Remarks” when necessary.

List non-conformities including deadlines for corresponding corrective actions if necessary.

		yes	partially	no
5.4	Is the equipment provided with a label or similar method indicating the next calibration/check?	☐	☐	☐
List of assessed documents:				
Remarks:				
Non-conformities:				

All measuring equipment used must have a label indicating the next date of calibration/check on it if possible. In case this is not possible it must be clearly identified by e.g. ID/serial no. and the list of measuring equipment (see 5.2).
Tick ”yes” in case the measuring equipment is clearly marked.
Tick ”no” in case the measuring equipment is not marked.
Tick ”partially” in case some are marked others are not marked.

List the documents assessed under ”List of assessed documents” and use ”Remarks” when necessary.

List non-conformities including deadlines for corresponding corrective actions if necessary.

		yes	partially	no
5.5	Do the calibration/check records indicate that calibration/check is traceable to national or international standards?	☐	☐	☐

List of assessed documents:	
Remarks:	
Non-conformities:	

Calibrations need to be traceable to national or international standards. For checks this is not necessary.
Tick ”yes” in case the calibration/check records are traceable to national or international standards.
Tick ”no” in case the calibration/check records are traceable to national or international standards
Tick ”partially” in case you find a situation between ”yes” and ”no”.

List the documents assessed under ”List of assessed documents” and use ”Remarks” when necessary.

List non-conformities including deadlines for corresponding corrective actions if necessary.

9 Control of production equipment

Section “6. Control of production equipment” is related to the Equipment used for production. Typical production equipment is e.g. welding machines, glass pane washing machines, two component silicone mixers, etc.
The section is separated in 3 different (6.1 to 6.3) blocks. These blocks are the following:

		yes	partially	no
6.1	Is there a documented procedure describing how to handle the production equipment?	☐	☐	☐
List of assessed documents:				
Remarks:				
Non-conformities:				

Documented procedures are required which describe the way the production equipment is handled and which regulates the responsibilities of the corresponding actions.
Tick ”yes” in case a documented procedure is available and all responsibilities are clearly defined.
Tick ”no” in case a documented procedure is not available.
Tick ”partially” in case you find a situation between ”yes” and ”no”.

List the documents assessed under ”List of assessed documents” and use ”Remarks” when necessary.

List non-conformities including deadlines for corresponding corrective actions if necessary.

		yes	partially	no
6.2	Is the relevant production equipment checked on a regular basis, such that in case of detection of a failure the previous production can be traced?	☐	☐	☐
List of assessed documents:				
Remarks:				
Non-conformities:				

The production equipment needs to be checked on a regular basis to ensure the well-functioning and to be able to trace back failures during previous production.
Tick ”yes” in case the production equipment is checked on a regular basis.
Tick ”no” in case the production equipment is not check on a regular basis.
Tick ”partially” in case you find a situation between ”yes” and ”no”.

List the documents assessed under ”List of assessed documents” and use ”Remarks” when necessary.

List non-conformities including deadlines for corresponding corrective actions if necessary.

		yes	partially	no
6.3	Are records about the function checks of the production equipment available? (Is the equipment provided with a label or similar method indicating the next check?)	☐	☐	☐
List of assessed documents:				
Remarks:				
Non-conformities:				

Records of the functional checks (see 6.2) need to be available and the equipment must be marked with a label indicating the date of the next check.
Tick ”yes” in case the records of the functional checks are available and the equipment is marked with a label indicating the date of the next check.
Tick ”no” in case the records of the functional checks are not available and the equipment is not marked with a label indicating the date of the next check.
Tick ”partially” in case you find a situation between ”yes” and ”no”.

List the documents assessed under ”List of assessed documents” and use ”Remarks” when necessary.

List non-conformities including deadlines for corresponding corrective actions if necessary.

10 Preservation of product

Section “7. Preservation of product” is related to the handling and storage of the final products and is separated in 2 different (7.1 to 7.2) blocks. These blocks are the following:

		yes	partially	no
7.1	Is there a documented procedure describing how to handle and store the final product?	☐	☐	☐
List of assessed documents:				
Remarks:				
Non-conformities:				

A documented procedure is required describing the handling/treatment and the storage of the finished product.
Tick ”yes” in case a procedure describing the handling and storage of the finished product is available.

Tick ”no” in case a procedure describing the handling and storage of the finished product is not available.
Tick ”partially” in case you find a situation between ”yes” and ”no”.

List the documents assessed under ”List of assessed documents” and use ”Remarks” when necessary.

List non-conformities including deadlines for corresponding corrective actions if necessary.

		yes	partially	no
7.2	After final inspection and test, are the products handled and stocked in such a way that compliance with the standards is not affected?	☐	☐	☐
List of assessed documents:				
Remarks:				
Non-conformities:				

After final inspection the products must be handled and stored in a way that they will not be damaged or otherwise changed to such an extent that the quality of the product is reduced in such a way that compliance with the standards is no longer guaranteed.
Tick ”yes” in case the handling and storage of the finished product is done in an appropriate way.
Tick ”no” in case a the handling and storage of the finished product is not appropriate.
Tick ”partially” in case you find a situation between ”yes” and ”no”.

List the documents assessed under ”List of assessed documents” and use ”Remarks” when necessary.

List non-conformities including deadlines for corresponding corrective actions if necessary.

11 Complaints

Section “8. Complaints” is related to complaints coming from the customers and/or installers and is separated in 3 different (8.1 to 8.3) blocks. These blocks are the following:

		yes	partially	no
8.1	Is there a documented procedure describing how to deal with complaints?	☐	☐	☐
List of assessed documents:				
Remarks:				
Non-conformities:				

A documented procedure is required describing the complaint management of the manufacturer.
Tick ”yes” in case a procedure describing the complaint management is available.
Tick ”no” in case a procedure describing the complaint management is not available.
Tick ”partially” in case you find a situation between ”yes” and ”no”.

List the documents assessed under ”List of assessed documents” and use ”Remarks” when necessary.

List non-conformities including deadlines for corresponding corrective actions if necessary.

		yes	partially	no
8.2	Are complaints concerning the certified products recorded?	☐	☐	☐
List of assessed documents:				
Remarks:				
Non-conformities:				

All complaints concerning the certified products must be recorded in an appropriate way. Appropriate ways are e.g. data bases, folders or spread sheets.
Tick ”yes” in case the complaints are recorded in an appropriate way.
Tick ”no” in case the complaints are not recorded in an appropriate way.
Tick ”partially” in case you find a situation between ”yes” and ”no”.

List the documents assessed under ”List of assessed documents” and use ”Remarks” when necessary.

List non-conformities including deadlines for corresponding corrective actions if necessary.

8.3	Are complaints evaluated and corrective actions taken if the complaints are relevant?	☐	☐	☐
List of assessed documents:				
Remarks:				
Non-conformities:				

To discover weaknesses in the product, production process or handling it is necessary to evaluate the complaints in such a way that appropriate corrective actions can be taken.
Tick ”yes” in case the complaints are evaluated and appropriate actions are taken.
Tick ”no” in case the complaints are not evaluated.
Tick ”partially” in case you find a situation between ”yes” and ”no”.

List the documents assessed under ”List of assessed documents” and use ”Remarks” when necessary.

List non-conformities including deadlines for corresponding corrective actions if necessary.

12 Storage of records

Section “9. Storage of records” is related to storage of records made during incoming goods inspection, production, etc. and is separated in 9 different (9.1 to 9.9) blocks. These blocks are the following:

		yes	partially	no
9.1	Is there a documented procedure describing how to handle records?	☐	☐	☐

List of assessed documents:	
Remarks:	
Non-conformities:	

A documented procedure is required describing how the manufacturer handles the records taken during incoming goods inspection, routine tests, non-conformities, function tests of production equipment, calibration/check of measuring equipment, customer complaints, internal audits and corrective/preventive actions.
Tick ”yes” in case a procedure describing the complaint management how to handle records is available.
Tick ”no” in case a procedure describing is not available.
Tick ”partially” in case you find a situation between ”yes” and ”no”.

List the documents assessed under ”List of assessed documents” and use ”Remarks” when necessary.

List non-conformities including deadlines for corresponding corrective actions if necessary.

		yes	partially	no
9.2	Are the records of the incoming goods inspection kept for at least 3 years?	☐	☐	☐
List of assessed documents:				
Remarks:				
Non-conformities:				

		yes	partially	no
9.3	Are the test records of the routine tests kept for at least 3 years?	☐	☐	☐
List of assessed documents:				
Remarks:				
Non-conformities:				

		yes	partially	no
9.4	Are the records of non-conformities and their evaluation kept for at least 3 years?	☐	☐	☐
List of assessed documents:				
Remarks:				
Non-conformities:				

		yes	partially	no
9.5	Are the records of calibration/check of the measuring equipment kept for at least 3 years?	☐	☐	☐
List of assessed documents:				
Remarks:				
Non-conformities:				

		yes	partially	no
9.6	Are the records of functioning checks of production equipment kept for at least 3 years?	☐	☐	☐

List of assessed documents:	
Remarks:	
Non-conformities:	

		yes	partially	no
9.7	Are the records of customer complaints and the corresponding corrective actions kept for at least 3 years?	☐	☐	☐

List of assessed documents:	
Remarks:	
Non-conformities:	

		yes	partially	no
9.8	Are the records of internal audits kept for at least 3 years?	☐	☐	☐

List of assessed documents:	
Remarks:	
Non-conformities:	

		yes	partially	no
9.9	Are the records of corrective / preventive actions kept for at least 3 years?	☐	☐	☐

List of assessed documents:	
Remarks:	
Non-conformities:	

All records mentioned in 9.2 to 9.9 must be kept for a time period of at least 3 years.
Tick ”yes” in case the corresponding record is kept for at least 3 years.
Tick ”no” in case the corresponding record is not kept for at least 3 years.
Tick ”partially” in case you find a situation between ”yes” and ”no”.

List the documents assessed under ”List of assessed documents” and use ”Remarks” when necessary.

List non-conformities including deadlines for corresponding corrective actions if necessary.

13 Corrective actions

Section “10. Corrective actions” is related to the completion of the corrective actions defined during the last inspection and is not relevant in case of an initial inspection (pre-license). In case the current inspection is performed by a different inspector than the previous one the previous factory inspection report must be available to the inspector.

		yes	partially	No
10.1	If there were any unsatisfactory findings entered in the previous inspection report, have they been corrected adequately? If initial inspection - not applicable.	☐	☐	☐
List of assessed documents:				
Remarks:				
Non-conformities:				

Corrective actions defined during the previous inspection must be completed within the defined time frame.
Tick ”yes” in case all corrective actions have been completed in the defined time frame.
Tick ”no” in case the none of the corrective actions have been completed in the defined time frame.
Tick ”partially” in case you find a situation between ”yes” and ”no”.

List the documents assessed under ”List of assessed documents” and use ”Remarks” when necessary.

List non-conformities including deadlines for corresponding corrective actions if necessary.

14 Change of certified product

Section “11. Change of certified product” is related to the procedures involved when the certified product is changed and is separated in 4 different (11.1 to 11.4) blocks. These blocks are the following:

		yes	partially	no
11.1	Is there a documented procedure describing how to deal with changes on certified products?	☐	☐	☐
List of assessed documents:				
Remarks:				
Non-conformities:				

A documented procedure is required that regulates the process of change to a certified product starting from the idea to the realisation.
Tick ”yes” in case an appropriate documented procedure is available.
Tick ”no” in case no appropriate documented procedure is available.
Tick ”partially” in case you find a situation between ”yes” and ”no”.

List the documents assessed under ”List of assessed documents” and use ”Remarks” when necessary.

List non-conformities including deadlines for corresponding corrective actions if necessary.

		yes	partially	no
11.2	Is there a documented procedure that ensures the report of changes to the certification body?	☐	☐	☐

List of assessed documents:	
Remarks:	
Non-conformities:	

A documented procedure is required that ensures that all changes to the certified product are reported to the certification body.
Tick ”yes” in case an appropriate documented procedure is available.
Tick ”no” in case no appropriate documented procedure is available.
Tick ”partially” in case you find a situation between ”yes” and ”no”.

List the documents assessed under ”List of assessed documents” and use ”Remarks” when necessary.

List non-conformities including deadlines for corresponding corrective actions if necessary.

		yes		no
11.3	Has the certified product been changed since the last assessment? If yes, list the changes performed. If initial inspection - not applicable.	☐		☐

List of assessed documents:	
Remarks:	
Non-conformities:	

In case the certified product was changed the manufacturer has to supply a list of changes.
Tick ”yes” in case the certified product was changed.
Tick ”no” in case the certified product was not changed.

List the documents assessed under ”List of assessed documents” and use ”Remarks” when necessary.

List non-conformities including deadlines for corresponding corrective actions if necessary.

		yes	partially	no
11.4	Were the changes reported to the certification body for approval? If initial inspection - not applicable.	☐	☐	☐

List of assessed documents:	
Remarks:	
Non-conformities:	

All changes of the certified products must be reported to the certification body for approval.
Tick ”yes” in case all changes have been reported to the certification body.
Tick ”no” in case no changes have been reported to the certification body.
Tick ”partially” in case you find a situation between ”yes” and ”no”.

List the documents assessed under ”List of assessed documents” and use ”Remarks” when necessary.

List non-conformities including deadlines for corresponding corrective actions if necessary.

15 Non-conformities

Section “12. Non-conformities” looks the following:

List all non-conformities and indicate the corrective actions the manufacturer needs to take.

1	***x.x* – Paragraph:** *corrective action:*
2	***x.x* – Paragraph:** *corrective action:*
3	***x.x* – Paragraph:** *corrective action:*
4	***x.x* – Paragraph:** *corrective action:.*

For non-conformities nn, supplementary documentation shall be presented to the inspection/certification body before 2010-xx-xx // before a Keymark certificate can be issued.

For non-conformities nn, supplementary documentation shall be available at the next factory inspection.

Here all non-conformities and the corrective actions are summarised. Please indicate also for each corrective action the time of fulfillment.

16 Recommendations

In section “13. Recommendations” the inspector has to give clear recommendations to the certification body with respect to the outcome of the factory inspection. The section “12 Recommendations” looks the following:

	Degree of criticism	**Required action**
1.	☐ No criticisms	---
2.	☐ Limited number of criticisms	Manufacturer shall confirm the implementation of the corrective actions to the inspector, certification proceeds. ***From the presented documentation it will be decided if an extra inspection will be needed.***
3.	☐ Criticism(s) to the extent that conformity with the standard is endangered	Factory inspection must be repeated after manufacturer has confirmed the implementation of the corrective actions.

Tick ”No criticism” in case no non-conformity was found.

Tick ”Limited number of criticisms” in case the non-conformities found do not endanger the conformity of the products to the standard/certification scheme and the corrective actions will be completed in time.
Tick ”Criticism(s) to the extent that conformity with the standard is endangered” in case the non-conformities found endanger the conformity of the product to the standard/certification scheme.

17 Signatures

The following shows the final signature section of the factory inspection report and is self-explanatory:

Two copies of the report are signed by the inspector and the factory representative. The factory representative accepts by signature the non-conformities. One signed copy of the report stays with the factory representative; the other one will be kept by the inspector who sends it to the certification body according to their agreement.

Date: yyyy-mm-dd

Name of inspector	Name of factory representative
_____	_____
Name	***Name***