Date	Description of modification	Revision number
14/12/2015	Initial version	1
19/03/2019	Deletion of paragraph related to testing according standards	2
06/12/2023	Revision of the definition of “manufacturing site” 1.2	3

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1 Factory Inspections

1.1 Introduction

The manufacturer/supplier shall have factory production control procedures (FPC) to ensure that products marked with the KEYMARK fulfil the requirements set out in these certification rules. These procedures shall be described in a quality manual based on the elements of ISO 9001, inspection instructions or corresponding document(s), and shall fulfil the requirements set out in the requirements below. Factory inspections are used to ensure that products meet and continue to meet the appropriate requirements described in this Annex and FPCs are in place and operating at each manufacturing site.

If the manufacturer/supplier has an ISO 9001 quality management system that has been certified by an accredited certification body, an abbreviated examination procedure in regard to the requirements below in respect of organization, document control, internal review, purchasing, corrective actions, storage, handling, packaging and transportation and complaints can take place.

1.2 Definition of manufacturing site

A manufacturing site is defined by the location of the final assembly of the refrigerant circuit or refrigerant circuit sub-assemblies (indoor/outdoor units).
All the sites where any final control test defined in point 2.4.2 are performed shall also be considered as manufacturing sites.

1.3 Initial Factory Inspection

The initial factory inspection shall cover the company's internal FPC documentation as well as inspection of the manufacturing site, how FPC procedures are implemented and their compliance with submitted descriptions etc.

Initial factory inspections start with an opening meeting to review the inspection requirements, to identify any Health and Safety issues and to establish any equipment that will be required. Inspectors check all aspects of the FPC process as required. The factory inspection will be reported in an appropriate report format. For any items which are found to be non-conforming with the requirements, as described in the report, the manufacturer shall present completed corrective actions (and where necessary objective evidence), within 45 days of the visit date.

At the end of the initial factory inspection, a brief closing meeting is held to confirm the scope of factory inspection and identify any non-conformities. Following the initial factory inspection, the inspector makes a recommendation for certification to either be granted subject to addressing any non-conformities within 45 days or for a full or partial re-inspection to be conducted.

1.4 Surveillance Factory Inspection

Product certificates are maintained and held in force through surveillance factory inspections and satisfactory completion of agreed product audit testing or product assessment where necessary. Surveillance factory inspections are conducted at least once a year but, depending on the outcome of the factory inspection, the certification body may require

additional factory inspections. The surveillance factory inspections are carried out to confirm that the FPC system operated by the company continues to meet the requirements. Where any non-conformities are raised corrective actions must be presented within 30 days. Where a major non-conformity is raised a re-inspection will be conducted (outside of the normal frequency of visits) within 12 weeks to check the corrective action. In extreme circumstances or where a major non-conformity is not adequately discharged, certification may be suspended immediately, by a decision from the empowered certification body.

2 Factory Production Control (FPC) – Requirements

2.1 General

This annex specifies the requirements for the Factory Production Control and the quality management system covering the production of heat pumps based on the elements of ISO 9001. The manufacturer/supplier shall have procedures (FPC) to ensure that products marked with the KEYMARK fulfil the requirements set out in these certification rules. FPC is used to ensure that products meet and continue to meet the appropriate requirements at each manufacturing site.

2.2 Organization

2.2.1 General

The FPC shall be operated according to a documented quality system. The manufacturer shall establish, document and maintain the FPC system to ensure that the products placed on the market comply with the certified product data. The records must be kept for at least a period of 3 years. All quality documentation shall be kept up to date.

2.2.2 Responsibility and Authority

The responsibility, authority, and the interrelationships between all personnel who manage, perform, or verify work affecting quality or product conformity, shall be defined. This applies particularly to personnel who need the organizational freedom and authority to:

a) Identify procedures to demonstrate conformity of the product at appropriate stages
b) Initiate action to prevent the use and production of non-conforming product
c) Identify and record any product quality problems or non-conformities

2.2.3 Management Representative for the FPC

At every place of production, a representative with the appropriate knowledge and production experience shall be appointed by the manufacturer and given responsibility for managing and supervising of the FPC procedures and for ensuring that the requirements of this annex are implemented and maintained.

2.2.4 Quality Objectives

Top management shall ensure that quality objectives regarding the production process are established at relevant functions and levels within the organization. The quality objectives shall be measurable.

There shall be at least one quality objective review every year.

2.2.5 Management Review

Management shall review at least every year the FPC system to ensure its continuing suitability, adequacy and effectiveness. Records of such reviews shall be maintained. The minimum input for management review shall be conformity of the product and include the following:

a) Status of corrective and preventive actions

b) Status of complaints

c) Follow up from previous management reviews

d) Follow up of quality objectives

e) Results of audits

2.2.6 Training of Personnel

The manufacturer shall establish and maintain procedures for the training (with a training plan and training records) of all personnel in activities affecting quality or product conformity. Personnel performing work affecting product conformity shall be qualified on the basis of appropriate education, training and/or experience, as required.

2.3 Quality Documentation

The manufacturer’s documentation and procedures shall be relevant and appropriate to the production and process control used during manufacture of the product, and shall provide at least the following items:

a) Quality aims or policy, the organizational structure, responsibilities and authority of the management with regard to product conformity

b) Procedures and results from management review

c) Procedures for contract review that takes into account customer requirements

d) Procedures for appointment of supplier and subcontractors and records of the appointed companies

e) Procedures for specifying and verifying the raw materials and other constituent materials

f) Production control and other techniques, processes and systematic actions that will be used

g) Inspections and tests to be carried out before, during and after production, together with their frequency and possible retest procedures

h) Procedures for handling, storage, packaging, marking and labelling the product

i) Procedures for how non-complying products shall be dealt with. Records from this shall be kept for a defined period. Procedures for corrective actions in order to eliminate the cause of non-conformities and to prevent recurrence.

j) Procedures shall be established to define the responsibilities and requirements for planning and conducting internal audits, establishing records and reporting results

k) Records of closeout handling of previous audits

l) The manufacturer shall have written procedures for ensuring traceability of products.

m) Procedures for control over the use of certification marks

n) Procedures for control over documentation that affects the FPC

o) Procedures for handling complaints

2.4 Inspection and Testing

2.4.1 Inspection and Testing of Raw Materials and other constituent Materials

The manufacturer shall ensure that raw materials and other constituent materials conform to their specified requirements. In determining the checks necessary consideration shall be given to the control exercised by the supplier and the documented evidence of conformity supplied (often referred to as supplier certified components or certified raw materials). There should be a proper traceability to the supplier's documentation.

2.4.2 Inspection and Testing during Manufacture and on finished Product

In order to manufacture products which conform to the certificate the manufacturer shall control their process and perform inspection and tests on each finalized item as described as follows.

Required tests:

- Leakage test of the refrigerant cycle EN 378-2
- Pressure test of the refrigerant cycle EN 378-2
- High voltage test EN 60335-1
- Test of ground conductor EN 60335-1
- Function/running test

2.4.3 Inspection and Test Records

The results of product inspection and testing shall be recorded
The record shall contain the product identification, the date and time of manufacture and for each property the test methods, the test results, the inspection result and the identification of the person carrying out the inspection.

2.5 Actions in Case of Non-conforming Products

If the result of a test or the inspection of a product is a failure, the manufacturer shall immediately take the steps necessary to rectify the deficiency. Products which do not conform to the requirements of the product standard, shall be marked, isolated or controlled accordingly. When the deficiency has been identified and rectified, the test or inspection in question shall be repeated without delay accordingly to the quality documentation, to provide the evidence that the defects have been overcome.

Corrective and preventive actions taken in case of non-conforming products shall be documented.

2.6 Handling, Storage, Packaging and Marking of Products

In accordance with the quality documentation the manufacturer shall:

a) Provide methods of handling that prevent damage or deterioration;
b) Provide suitable storage areas or stock rooms that prevent damage or deterioration of the product;
c) Control the packaging, storage and the marking processes

2.7 Traceability of Products

Individual heat pumps and their main components shall be identifiable and traceable with regard to their production origin.

2.8 Internal Audit

The organization shall conduct internal audits at planned intervals of at least once a year to determine whether the quality management system:

a) Conforms to the quality documentation
b) Is effectively implemented and maintained

Records of the audits and their results shall be maintained.

Follow up activities shall include the verification of the actions taken and the reporting of verification results.