Heat Pump KEYMARK

STROJÍRENSKÝ ZKUŠEBNÍ ÚSTAV

FACTORY PRODUCTION CONTROL (FPC) – REPORT

No. 32-10253/HPK

Inspection Body:	Strojírenský zkušební ústav, s.p. (SZU) Hudcova 424/56b 621 00, Brno Czech Republic
Manufacturer:	Master Therm tepelná čerpadla s.r.o. Václavské náměstí 819/43 110 00 Praha 1 - Nové Město Czech Republic
Production site:	Hradsko 183 512 43, Jablonec nad Jizerou Czech Republic
Product:	Heat pumps - Outdoor Air/Water - Brine/Water
Sub-type(s) and model(s):	BoxAir Inverter BA22I (BoxAir Inverter BA22I) BoxAir Inverter BA26I (BoxAir Inverter BA26I) BoxAir Inverter BA37I (BoxAir Inverter BA37I) BoxAir Inverter BA45I (BoxAir Inverter BA45I) AquaMaster Inverter AQ17I (AquaMaster Inverter AQ17I) AquaMaster Inverter AQ22I (AquaMaster Inverter AQ22I)
Auditor:	Michal Manhalter Mario Jankola
Date of audit:	2020-08-19
Audited requirements:	Heat pump KEYMARK Scheme: Annex B – Requirements for Factory Inspections and Factory Production Control (FPC); Rev. No. 2
Date of report issue:	2020-08-19

1 General

Date of inspection	2020-08-19
Type of inspection	☒ Initial (pre-licence) ☐ Follow-up ☐ Sample selection
Report No. and date of last inspection	– (initial certification)
Holder of the certificate(s) *(fill in company name and full address or make reference to "Issued to:" above)*	Master Therm tepelná čerpadla s.r.o. Václavské náměstí 819/43 110 00 Praha 1 - Nové Město Czech Republic
Certificate No.	– (initial certification)
Manufacturer's registered name and factory location	**Registered name:** Master Therm tepelná čerpadla s.r.o. Václavské náměstí 819/43 110 00 Praha 1 - Nové Město Czech Republic **Factory location:** Hradsko 183 512 43, Jablonec nad Jizerou Czech Republic
Names and positions of person(s) seen in the factory	Ing. Zdeněk Vomáčka Ing. Jiří Jiránek
Number of non-conformities (see also 10)	1

2 Quality system

2.1	Quality system	yes	no
	Does the manufacturer hold a certified quality management system that includes the products in question? Is it adequate for the products in question?	☒	☐
Certification no.:	CZ008341-1		
Date of expiry:	2022-07-10		
Remarks:	The company's QM System is implemented and certified. The main document is quality manual S-01 of 2018-06-01. QMS is certified by Bureau Veritas Certification CZ, certificate number CZ008341-1, date of expiry 2022-07-10. The company's ERP system is Helios. This software is used for all the QMS parts, included production. CRM in Helios is used only partly because of the cooperation with the service technicians and sales. All the QMS documents are available in central server storage for view. All current drawings and production documentations are kept in central server storage. The drawings have a revision number. Older one are kept on the server as well.		

3 Organisation

3.1	Organisation	yes	no
a)	Is the organisational structure, responsibilities and authority of the management adequate for the products in question?	☒	☐
b)	Is there sufficient documentation?	☒	☐
Assessed documents:	S01-D05		
Remarks:			

3.2	Responsibility and authority	yes	no
a)	Are responsibilities and authority of the management with regard to product, management clearly defined? Is it clear who has the responsibility to take actions regarding product conformity?	☒	☐
b)	Is there sufficient documentation?	☒	☐
Assessed documents:	S01 (Směrnice Příručka kvality)		
Remarks:	The responsible person of product conformity is Mr. Jiránek. The responsibilities and authorities are described in S01, Article 5.3		

3.3	Management representative for the FPC	yes	no
a)	Is it clear who the management representative is?	☒	☐
b)	Is there sufficient documentation?	☒	☐
Assessed documents:	S01 (Směrnice Příručka kvality) S01-D05 (Organizační struktura)		

Remarks:	Management representative for the FPC is Mr. Zdeněk Vomáčka.

3.4	Quality objectives	yes	no
a)	Are there quality objectives that are relevant?	☒	☐
b)	Is there sufficient documentation?	☒	☐
Assessed documents:	R01-20 (Cíle kvality na rok 2020) S01-D01-19 (Zpráva o stavu SMK za rok 2019)		
Remarks:	Quality objectives for 2020 seen – there were 8 quality objectives. Some of them are from 2019. Evaluation of the quality objectives is a part of the management review.		

3.5	Management review	yes	no
a)	Is there a procedure for management review? Has it been performed? Is the content adequate?	☒	☐
b)	Is there sufficient documentation?	☒	☐
Assessed documents:	S01-D01-19 (Zpráva o stavu SMK za rok 2019) S01-D02-19 (Zápis z porady vedení o přezkoumání SMK za období 2019)		
Remarks:	Management review is conducted yearly. Management review for 2019 seen included meeting minutes.		

4 Procedures and documentation

4.1	Document control	yes	No
a)	Are there procedures for control of documentation affecting the FPC, such as updating, approval and publishing of procedures?	☒	☐
b)	Are there procedures for archiving and archiving times of records?	☒	☐
Assessed documents:	S02 (Řízení dokumentu) S09 (Směrnice Řízení, zpracování výrobní dokumentace) S10 (Řízení záznamů) SD 06-01 (Výrobní list TČ)		
Remarks:	Document control is described in S02. Control of FPC documentation is described in S02, Article 3.3. All the QMS documents are available in central server storage for view. Production documentation and drawings can be changed and approved only by Mr. Jiránek. It is described in S09. For an updating of the technical standard is used "ČSN online". Archiving procedure is described in S09. Archiving times are described in document "Skartační plán". All the production lists (SD 06-01) have been archived in paper and scan versions (central server storage) since the very beginning of the production (2005). Checked case: Production list – Thermal 20140146		

4.2	Contract review	yes	no
	Are there procedures for contract review that take into account customer requirements? Are they followed correctly?	☒	☐
Assessed documents:	S13 (Směrnice Prodej)		

Remarks:	The company works mostly in B2B market. Sale partners have conducted a General Contract with the company. The partner has a contract with the end customer. Then the partner orders the product(s) via post mail or e-mail. After the order review (S13, Article 8.1) the reservation for the production is made. When the order is reserved in the production, the confirmation is send to the partner. All the process is made in Helios system. Checked case: Order Confirmation no. 200378, Thermal Earth Ltd.

4.3	Suppliers and subcontractors	yes	no
	Are there procedures for assessment of suppliers and subcontractors? Are there records?	☒	☐
Assessed documents:	S05 (Směrnice Nakupování) S05-D02-19 (Hodnocení dodavatelů materiálu a zboží pro výrobu a montáže za rok 2019)		
Remarks:	Evaluation of suppliers and subcontractors is described in S05, Article 4. Evaluation of 2019 seen (central server storage).		

4.4	Materials and components	yes	no
	Are there procedures for specifying and verifying the raw materials and other constituent materials?	☒	☐
Assessed documents:	Drawings of components and raw materials (central server storage)		
Remarks:	Component lists, drawings and raw materials are kept in central server storage. Verification is performed during inter operational and final check.		

4.5	Production control	yes	no
	Are there procedures for production control, including inspections and tests that are performed before, during and after production?	☒	☐
Assessed documents:	S06 (Směrnice Řízení výrobního procesu) S08 (Řízení neshodných výrobků) S11-D05 (Kódy pracovních operací)		
Remarks:	see 5.2, 5.3 and 5.4		

4.6	Handling of finished products	yes	no
	Are there procedures for handling, packaging and storage of finished products?	☒	☐
Assessed documents:	S12 (Balení) S11-D05 (Kódy pracovních operací)		
Remarks:	Handling, packaging and storage of finished products are operating code 6102.		

4.7	Non-complying products	yes	no
a)	Are there procedures that specify how non-complying products shall be dealt with and how long records shall be kept?	☒	☐
b)	Are there records?	☒	☐
Assessed documents:	S08 (Řízení neshodných výrobků)		

Remarks:	Each non-complying product is being repaired. Non-complying can be only a component. Non-complying component is recorded to "Výdejka". Checked case: Carel s.r.o. (2020-08-18)

4.8	Traceability	yes	no
	Are there procedures for ensuring traceability of products?	☒	☐
Assessed documents:	SD06-01		
Remarks:	Any product can be traced with the serial number. Based on this number can be found the actual production list. On the list and in Helios system can be found specific component list. Checked: Serial number AQI2201714		

4.9	Certification marks	yes	no
	Are there procedures regarding the use of certification marks?	☐	☒
Assessed documents:			
Remarks:	This procedure has not been implemented yet. It will be check during next surveillance FPC (see 10.1).		

4.10	Non-conformities and corrective actions	yes	no
a)	Are there procedures for implementing corrective actions to eliminate the cause of non-conformities, in order to prevent recurrence?	☒	☐
b)	Are records of non-conformities, together with their evaluation and corrective actions, kept for at least 3 years?	☒	☐
Assessed documents:	S04 (Směrnice Opatření k nápravě, preventivní opatření) S01-D03-19 (Vyhodnocení reklamací za rok 2019) S01-D04-19 (Seznam záručních servisních zásahů za rok 2019)		
Remarks:	Reasons of non-conformities are evaluated yearly. Checked case: Preventive action J 12-01		

4.11	Internal audits	yes	no
	Are there procedures for internal audits, including planning, conducting, recording and handling of discovered non-conformities?	☒	☐
Assessed documents:	S03 (Směrnice Interní audity) "Plán interních auditu SMK" of 2020-01-28		
Remarks:	Internal audits are made by external consulting company yearly.		

4.12	Previous audits	yes	no
	Are there procedures for closing non-conformities from previous audits?	☒	☐
Assessed documents:	S03 (Směrnice Interní audity)		
Remarks:			

4.13	Complaints	yes	no
a)	Are there procedures for handling customer complaints?	☒	☐
b)	Are records of customer complaints and the corresponding corrective	☒	☐

	actions kept for at least 3 years?		
Assessed documents:	S08 (Řízení neshodných výrobků) S01-D03-19 (Vyhodnocení reklamací za rok 2019) "Objednávka a protokol o provedení servisního zásahu" no. 12196		
Remarks:	Records of customer complaints are kept forever in software Helios. Checked case: 012196, Zbyněk Nový, error of temperature sensor, 2020-08-05 (Serial number EM2600616)		

4.14	Training and qualification	yes	no
a)	Are there procedures for training and qualification of staff?	☒	☐
b)	Is it documented which staff is qualified for operations that can affect product quality?	☒	☐
Assessed documents:	S11-D01-20 (Plán školicích aktivit) Certificate 1657/14 of 09-06-2014 (Zákon č. 73/2012 Sb. and ES 303/2008) "Kvalifikační karta pracovníka" SD11-02		
Remarks:	Each staff has their own list with information about the qualifications. Checked: - Michal Poslušný, brazing certificate 2-185727-B - Jaroslav Metelka, electrical qualification 2019/02/02		

5 Inspection and testing

5.1	Production during visit	yes	no
	Were the products included in the certification or intended for certification in production at the time of the visit? *If "Yes", identify product name and any cert.no. that appeared on them.*	☐	☒
Products in production:	AquaMaster AQ90Z (SN: AQ9000120)		
Remarks:	Brine(Water)/Water heat pump		

5.2	Inspection before production	yes	no
a)	Are specifications and/or drawings of raw materials and components available for checking?	☒	☐
b)	Does the manufacturer ensure that the incoming materials/products and/or subcontracted services are in conformity with the specified requirements?	☒	☐
c)	Are non-conforming materials clearly identified and/or segregated to prevent any unauthorised use?	☒	☐
Assessed documents:	S08 (Řízení neshodných výrobků)		
Remarks:	All the process is described in S08.		

5.3	Inspection during production	yes	no
a)	Are updated versions of relevant documents available to production staff, e. g. procedures, quality plans, inspection and test-instructions, photographs, drawings or samples for all operations/parts that have an impact on the conformity of the finished products?	☒	☐
b)	Are there instructions describing how to handle the production equipment?	☒	☐
c)	Is there a documented procedure describing the measurements and tests performed during the whole production process?	☒	☐
d)	Are there appropriate records available for all checks and tests performed during the production?	☒	☐
e)	Is there a documented procedure describing how to handle non-conforming products and are they clearly identified and/or segregated to prevent any unauthorized use?	☒	☐
Assessed documents:	"Výrobní list TČ" S08 (Řízení neshodných výrobků) S06 (Směrnice Řízení výrobního procesu)		
Remarks:	Production staff has a drawings and test-instructions. Each of production staff is trained and qualified for the each specific operation. All the non-confirming products are repaired immediately. Segregated non-confirming parts are only components and raw material.		

5.4	Testing of finished product	yes	no
	Are these required tests performed on each produced unit? — 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		
Products in production:	AquaMaster AQ90Z (SN: AQ9000120)		
Assessed documents:	"Těstnostní zkouška N2 (Frigo) 4997_1 "Zkušební postup" of 2016-03-07		
Remarks:	For the leakage and pressure tests is used nitrogen with pressure based on the specific drawing of the refrigerant circuit. Limits for high voltage test and test of ground conductor are specified in production list. Electrical tests and function/running tests are described in document "Zkušební postup".		

5.5	Inspection Records	yes	no
a)	Are records from inspections and tests, before during and after production, kept for at least 3 years?	☒	☐
Assessed documents:			
Remarks:	Production lists are kept in central server storage forever.		

5.6	Handling and marking of finished products	yes	no
a)	After final inspection and test, are the products handled and stored in such a way that their compliance with the standards is not affected?	☒	☐
b)	Are certified products marked according to the scheme rules?	☐	☒
Checked products:	AquaMaster AQ90Z (SN: AQ9000120)		
Remarks:	b) Products have not been certified yet.		

6 Handling of measuring equipment

6.1	Documented Procedure	yes	no
	Is there a documented procedure describing how to handle measuring equipment including the responsibilities related?	☒	☐
Assessed documents:	S07 (Směrnice Metrologie)		
Remarks:			

6.2	Equipment and identification	yes	no
a)	Is a list with all equipment used for measurements available?	☒	☐
b)	Is all measuring equipment clearly marked with ID and calibration status?	☒	☐
Assessed documents:	SD07-01 (list of equipment) "Kalibrační a kontrolní list měřidla" SD07-02		
Remarks:	All the calibration are valid. Checked: - Manometer, M2014-01 - Electrical measuring device Revex Plus, K017E - Scale 694090, LPV-E180-18		

6.3	Calibration / function check	yes	no
a)	Is the relevant measuring equipment used in all stages of the factory production control calibrated and/or checked?	☒	☐
b)	Are records of calibration and function check kept for at least 3 years?	☒	☐
c)	Is calibration/function check traceable to national or international standards?	☒	☐
d)	Is the time for next calibration/check clearly documented?	☒	☐
Assessed documents:	"Kalibrační a kontrolní list měřidla" SD07-02		
Remarks:			

7 Follow-up of previous audits

7.1	Handling of non-conformities	yes	no
	Have possible non-conformities from previous audits been handled and corrected adequately? (If initial inspection, not applicable.)	☐	☒
Assessed documents:			
Remarks:	Initial inspection – not applicable		

8 Changes to Certified Product

8.1	Documented Procedure	yes	no
	Is there a documented procedure describing how to deal with changes on certified products?	☐	☒
Assessed documents:			
Remarks:	Initial inspection – not applicable		

8.2	Changes	yes	no
	Has any certified product been changed since the last assessment? If yes, list the changes performed. (If initial inspection, not applicable.)	☐	☒
Assessed documents:			
Remarks:	Initial inspection – not applicable		

8.3	Report of Changes	yes	no
	If yes on question 8.2, were the changes reported to the certification body for approval? (If initial inspection, not applicable.)	☐	☒
Assessed documents:			
Remarks:	Initial inspection – not applicable		

9 Documentation, storage of records

9.1	Inspection Records	yes	no
	Are the records of the inspection before production kept for at least 3 years?	☒	☐

Assessed documents:	
Remarks:	

9.2	Calibration Records	yes	no
	Are the records of calibration/check of the measuring equipment kept for at least 3 years?	☒	☐
Assessed documents:			
Remarks:			

9.3	Functional Checks Records	yes	no
	Are the records of functioning checks of production equipment kept for at least 3 years?	☒	☐
Assessed documents:			
Remarks:			

9.4	Non-conformity Records	yes	no
	Are the records of non-conformities and their evaluation kept for at least 3 years?	☒	☐
Assessed documents:			
Remarks:			

9.5	Complaints Records	yes	no
	Are the records of customer complaints and the corresponding corrective actions kept for at least 3 years?	☒	☐
Assessed documents:			
Remarks:			

9.6	Corrective/Preventive Actions Records	yes	no
	Are the records of corrective/preventive actions kept for at least 3 years?	☒	☐
Assessed documents:			
Remarks:			

10 Non-conformities and observations

10.1	Non-conformities
1	Make a procedure for certification marks (see 4.9) with focusing on marking and labelling of the certified products.

~~**For non-conformities no. X-Y, corrective actions shall be performed and reported to the inspection body within 30 days (45 days for initial inspection), no later than 20YY-MM-DD.**~~

For non-conformity no. 1, the manufacturer shall implement corrective actions which will be followed-up at next inspection.

10.2	Observations
1	Manometer with a more detailed scale.
2	Test-instruction should be revised according to reality and divided into parts for each testing workplace.

Observations are to be seen as suggestions of improvement, or as items that might need to be followed-up at future inspections. Reporting of corrective actions is not necessary.

11 Recommendation

	Degree of criticism	Required action
1	☒ No criticisms	No action is required
2	☐ Limited number of criticisms	Continued certification is recommended. The manufacturer shall report the implementation of corrective actions for observed non-conformities, see item 9.1. 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	A new factory inspection must be performed after that the manufacturer has confirmed the implementation of the corrective actions.

12 General and Other Remarks/Comments

Any relevant remarks not included in the previous questions should be given here.

1	No remarks or comments

This report is signed both by the inspector and by the factory representative.
By signing, the factory representative accepts the non-conformities and the report content.

The inspector sends a copy to the certification body according to their agreement.

Date: **2020-08-19**

Signature of inspector(s):

Ing. Michal Manhalter
Ing. Mario Jankola

Signature of factory representative:

Ing. Zdeněk Vomáčka
Ing. Jiří Jiránek