Audit Report

According to Directive 2013/29/EU

Audit Report Number:	**QAR21.0076**
Manufacturer (auditee):	MAUS Falkenheim Invest AB Sockerbruksgatan 20 531 40 LIDKÖPING SWEDEN
Production Site(s) audited:	MAUS Falkenheim Invest AB Sockerbruksgatan 20 531 40 LIDKÖPING SWEDEN
Product description (range):	Pyrotechnic articles according to the list of certificates
No. of Employees:	3/3
Scope of Audit:	Initial Assessment ☒ Re-Assessment (surveillance) ☐
Type of products:	Pyrotechnic articles category P1
Audit Team Leader:	Harald Herzig
Date of Audit:	18th and 19th November 2021
Date of Report:	09th December 2021

PB.21.CRT.403/HZ/MM

Audit Team Leader
(Signature)

Certification department
Approved

Fiditas d.o.o. ZAGREB

Mario Mačković

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CONTENTS

1 SUMMARY REPORT

Assessment Summary and Conclusions:
State the most important results and conclusions of the assessment

This report refers to the initial audit of the manufacturer's quality system according to Module E of Directive 2013/29/EU.The initial audit was carried out on November 18th and 19th, 2021 for the company Falkenheim Invest AB; Sockerbruksgatan 20, 531 40 Lidköping in Sweden.
The quality system of the company Falkenheim Invest AB, includes all processes required for product quality. The quality management system is based on ISO EN 9001, but mainly refers only to the processes that are necessary to ensure the quality inspection. However, these necessary processes are all clearly and unambiguously regulated. The quality management system was created by the company and released as of 01.11.2021.
Thus, the product quality required by the directive and the standards, especially the product safety, is given.

The assessment is carried out for the manufacture and final testing of pyrotechnic articles of categories P1 according to Module E of Directive 2013/29/EU. The assessment refers to pyrotechnic articles certified by the Federal Office for Research and Testing (BAM in Germany), according to the list of certified pyrotechnic articles.

Based on the results the assessment carried out in accordance with the Directive and the applicable standards for the above pyrotechnic articles, the company's quality management system complies with Module E of Directive 2013/29/EU. Since the assessment of the quality management system is carried out on a random basis, there may be deviations that were not detected during the audit. Undetermined facts do not release the organization from its responsibility for continuous compliance with all requirements Module E of Directive 2013/29/EU.

Non-Conformities:

NCR 1
EU declaration of conformity for products do not follow the requirements of ANNEX III of the directive 2013/29/EU.

With implemented corrective actions the nonconformities are corrected (separate records of nonconformity).

Audit Team Leader Recommendations

☒ **Certification to be issued**

☐ **Certification to be issued** following receipt of satisfactory documentary evidence supporting effective corrective action, and a test report is issued. Corrective action to be verified at next surveillance visit.

☐ **Certification to be issued following a satisfactory follow-up visit** and verification that corrective actions have been effectively documented and implemented, and test report issued.

☐ **Certification to be refused/suspended** A further complete assessment to be conducted.

☐ **Certification to be refused/suspended** Close the application/withdraw the notification and inform the Scheme Administrator.

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2 AUDIT INFORMATION

Scope of Audit:

initial assessment of manufacturer with a certified QMS	☐
initial assessment of manufacturer without a certified QMS	☒
reassessment (surveillance) of manufacturer with a certified QMS	☐
reassessment (surveillance) of manufacturer without a certified QMS	☐
assessment, reassessment or surveillance of manufacturer including to ISO 9001	☐

QM System

Basis: -
Certification body: -
Certificate valid until: -
Certificate No.: -

Audit Criteria:
List any other reference documents, against which Audit was conducted

Reference
Directive 2013/29/EU
Applied standards according to the type certificate

Duration of audit: 2 auditor days
Indicate total number of auditor days on site

Composition of Audit Team:

Name	Role in Audit (*Team Leader, Auditor, Technical Specialist, etc*)
Harald Herzig	Team Leader, Auditor, Technical Specialist

Interviewed Representatives of Manufacturer (Auditee):
Include name and position

Name	Position
Andreas Norlin	Director, responsible person
Roni Sandgren	Employee
Tommy Carlsson	Employee

Type categories tested from Manufacturer:
P1

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3 OBSERVATIONS

Organization and responsible persons:

The organizational structure of the company is documented in the quality manual. There are clearly defined responsibilities and authorities for each function with which the employees are familiar.

Quality control of the products is directly setled under the CIO of Falkenheim Invest and is directly connected with the managing director. The employees who carry out the quality inspections are trained and educated according to their tasks.

Additional responsibilities and authorities are defined according to Quality Manual and organizational chart and the following persons are appointed:

Person responsible for documentation, product and certificate:

1. Responsible person: Andreas Norlin
2. Responsible person: Roni Sandgren

Person responsible for quality management system:

1. Responsible person: Andreas Norlin
2. Responsible person: -

Person responsible for control of explosive materials products:

1. Responsible person: Roni Sandgren
2. Responsible person: Tommy Carlsson

Person responsible for final marking:

1. Responsible person: Andreas Norlin
2. Responsible person: -

The number of overall people employed in the company are 3 persons.
The number of overall people employed at testing pyrotechnic articles are 2 persons.
There is no need of any external stuff for the batch testing process.

Quality management system:

The organization has documented and implemented a quality management system according to Module E of Directive 2013/29/EU. The quality management system is not certified according to ISO 9001.
The quality management system includes, among others, the following:
- The control of documents, including their recording and their handling in case of changes.
- Control and handling of defects,
- Corrective actions
- Preventive measures
- Recall of products
- The procurement of products

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- Quality objectives
- Complaints
- Testing and measuring equipment and their handling
- Detailed work instructions for product testing, concerning for example the drawing of test samples, the performance of the test, the handling of the test equipment, etc.
- Detailed test report that allows recording of results and exact allocation.

All documents are listed in the manual.

Quality system documentation:

The organization has documented and implemented a Quality Manual which includes the manufacture of pyrotechnic articles and is in accordance with the requests shown of Modul E in the Directive 2013/29/EU. Thereunder are defined documents at lower levels in the quality management system (i.e. documented procedures, work instructions, control plans and etc.) which define all the necessary information in accordance with the requirements of Modul E Directive 2013/29/EU.

Quality policy and quality objectives:

The quality policy has been established and all employees of Falkenheim Invest AB are familiar with it. The suitability of the quality policy is evaluated annually by the management.
The quality objectives have been properly planned in accordance with the existing quality policy and will be amended or added to as necessary, with clear criteria for monitoring and measuring performance.

Identification and process management:

Falkenheim Invest AB has clearly identified all processes within its organization and these processes are described by processes, work and control instructions and other documents.
The production of pyrotechnic items takes place in China and is organized independently by Falkenheim Invest. The storage area is located at Falkenheim Invest AB's site in Lidköping.
The warehouse for finished pyrotechnic articles prepared for delivery is also located at Falkenheim Invest AB's site in Lidköping.
Testing of finished pyrotechnic articles is carried out at the test site at the same Falkenheim Invest AB location in Lidköping.

The company Falkenheim Invest AB acts as the manufacturer and is therefore the holder of the type approvals and is subject to the European Directive 2013/29/EU as the manufacturer and is therefore responsible for quality assurance. After delivery, Falkenheim Invest AB performs a test according to a test procedure based on the product standard EN 16263 and the corresponding sub-type of the finished pyrotechnic product. The batch test is performed for each new batch. This is done in accordance with the relevant standards and specifications of Directive 2013/29/EU. The test quantity "n" is determined depending on the total number of products produced in this batch (batch size) and is drawn with a fixed procedure, which is documented in a work instruction. All inspections and tests are carried out in accordance with the quality guidelines and other quality system documents (documented procedures, work instructions, control plans). The relevant inspection sheets correspond to the individual inspection points in accordance with the specifications of the product standard required for the batch inspection.

Each consignment of pyrotechnic articles is accompanied by Falkenheim Invest AB's declaration of conformity and the relevant instructions for use in accordance with the EU type examination certificates.

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Customer satisfaction:

The Falkenheim Invest company carries out the evaluation of customer satisfaction through direct conversations with its customers. Suggestions or criticisms are implemented due to the small size of the company and flat hierarchy, if they fit into the concept, or process of Falkenheim Invest, there is a corresponding regulation for this.

Organizational structure:

The organizational structure of the company Falkenheim Invest, the responsibilities and authorities of the management and employees in relation to product quality are shown in the company's organizational chart. (ORG).

Continual improvement:

Continuous improvement will be carried out based on proposals for improvements that occur within the organization by employees or as a result of internal and external assessments.
The suggestions are reviewed and appropriate measures are initiated on the basis of the assessment.

Fullfilment of regulatory requirements:

The company is a manufacturer and distributor of fire extinguishing products and accessories for fire fighting. The company was registered at the district court of Göthenburg, register number 5590361472 in the year 2015.

To meet the requirements and ensure the conformity of its products, the company Falkenheim Invest has the necessary technical literature and standards.

Assessment of staff technical background for final product inspection and testing:

A training status plan is maintained on the current training and knowledge status of each employee. This plan shows the current level of training and knowledge for each employee.

Testing permisses, final inspection and testing reports and practicing results:

The assignment for the test product inspection has been issued by the management to two employees.
These were interviewed regarding their suitability to carry out the necessary test processes during the audit.
During the audit, an inspection of a batch size was performed with existing test samples. The size of the lot was set by the auditor at 650 pieces.
The two audit participants, Mr. Carlsson and Mr. Sandgreen, who practicing the lot size inspection were able to explain to the auditor the sample picking procedure for their test samples (procedure of a picking of test samples "n").
They knew the working instruction WI06 (sample picking procedure) prepared by the company Falkenheim Invest for the picking of test samples. They were able to explain the individual steps of the procedure and to justify it. In response to the auditor's questions why the samples must be taken from different packages and in the specified maximum number of pieces defined in there documents, they gave concrete and correct answers.
The further audit showed that the inspection of the test samples with the specifications of the type was carried out in a professional manner. The inspectors carried out the inspection of the test samples with the specifications of the type test by using the appropriate test equipment, like digital calipers, scales. The test equipment is marked and shows the date of the next calibration to be performed.
The two inspectors use the measuring and test equipment accordingly to its described use (Working instructions WI).
They can also provide information on how to deal with possible defects of measuring and testing equipment.
The measured values were documented accordingly by the testers in the BT 101 test report.

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The test samples were placed in an appropriate order after measurement. The auditor recommends marking the test samples with a waterproof pen to prevent possible confusion in the sequence.

With regard to the labeling, the participants were able to provide information about the labeling requirements and the necessary minimum font sizes. These are also listed in the BT101 test report. The quality inspectors were able to demonstrate how they measure the font sizes and the size of the CE mark.

The tests of the product parameters were carried out in three test boxes (tests creens). The performance parameters for the test samples were carried out in a test box with the appropriate volume of 0.1 m^3. The two product testers also paid attention to possible explosive decompositions, recorded the performance parameters, such as the time span of aerosol release, and subsequently assessed the object with regard to the complete implementation of the effect and any new openings on the effect body caused by the effect output.
The release time was determined in a separate test process for which the number of test samples n was doubled. A third testprocedure was also carried out with 10 additional test specimens with regard to possible dangerous debrises.

The two product testers were able to provide correct information in response to questions from the auditor regarding fault evaluation.

Evaluate the technical background of personnel for final inspection and testing of products:

The product tests carried out have practiced correct and carried out by well-trained employees.
All necessary work instructions from the drawing of inspection lots to the release or possible blocking of the lot are regulated. In order to avoid mixing of new, untested goods with already tested goods in the warehouse, it is recommended to introduce a goods receipt label for the pallets or storage blocks, on which a release can be noted, or obviously the goods are blocked until release.

Management of measuring equipment.

The measuring equipment is listed in a separat form.
During the audit, the following test equipment was checked.
a) A digital caliper. It´s documentation can be found with proof of calibration in the list of test and measuring equipment.
b) A digital stopwatch. Its documentation can also be found with proof of calibration in the list of test and measuring equipment.

Final inspection and testing (test certificate).
During the Practical Test of Test Capability, the article MAUS - Fire Suppression Sticker MAUS STIXX certificate number 0589.PYR.2448/19 with reference number 0589-P1-1277 was tested. The test was performed correctly as previously described, and the test report completed by the staff was kept on file as a copy.
The test complied with the requirements of the EN 16263 standard.
The performance parameters that were specified were
- release time (<5 seconds), the release and conversion (release of the aerosol), the performance parameter of the release of the aerosol in a container with a given maximum size and volume, the complete function and the presence of possible burning particles. The test was carried out by means of three test containers designed by Falkenheim Invest in accordance with the EN 16263 standards and their performance parameters. A measurement of the sound pressure is not recorded, because the test procedures are all carried out in closed containers. A control measurement by the auditor on the unencapsulated (exposed) object resulted a sound pressure of approximately 77 db AI The measurement of the sound pressure on the closed container, as would be done during the tests, did not give results that exceeded the general room noise level. This was consistent with the recordings provided by Maus. As a result of the measured sound pressure and the associated unnecessary labeling of possible acoustic hazards resulting from the standard (EN16263). A sonic consideration of the object in the batch test is not meaningful. The quality assurance system of Falkenheim invest guarantees the conformity of the products with the type described in the EU type-examination certificate and with the requirements of Directive 2013/29/EU applicable to them.

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Remarks/recommendations:

During the assessment of the quality management system there have been found certain remarks (opportunities for improvement) which, if ignored, can lead to inefficiencies and inconsistencies in the quality management system and it is therefore necessary to analyze them and take appropriate actions. Evaluation of taken actions will be done during next assessment.

Remark 1:

Marking of test samples by practicing the test with an waterprofed pen.

Remark 2:

When pyrotechnical items (aerosol generators) will be added in the portfolio, the testequipment for these items must fulfill their special performance parameters. (like aerosol output/ volume of the aerosol output) and its functionallity.

Remark 3:

The Labeling is done a) on the item itself under the requirements of EN 16263-5 4.13 Marking of very small items (with the CE mark and the NOBO number [2829] pressed in the plastic body (under the request of EN 16263-5 no. 4.12 Printing). b)The marking of the primary pack is done under the Request of EN 16263-5 no 4.1, 4.2, 4.3, 4.4, 4.6, 4.7, 4.11, (4.13) and 4.12. So that the relevant informations for identifying and selling (age limit, must be supplied as packeged etc.) are given. In fact that the item packing is although very small the manufacturer adds the information, that the handling instructions and other parameters will placed on an paper inside the packing. c) the complete labeling requested for the item is still placed a separate in lay paper, which shows although with graphics the compelte handling. Audit note to Remark3:
The application of the labeling as practiced by Falkenheim Invest is acceptable to the auditor even with this deviation from the standard specification. However, it should be noted that the compliance with the labeling specifications is the obligation of the manufacturer. A claim of the manufacturer for correctness of the labeling by the Audit is not derivable.

Remark 4

Application of marking of newly arrived goods. Newly arrived goods shell be marked with a "blocking" sticker (Marking of pallets or boxes), to prevent mixing with inspected goods, or possible delivery before the batch size inspection.

4 ANNEX A: LIST OF CERTIFIED PYROTECHNIC ARTICLES

Items:
Maus Stixx; Registration no. 0589-P1-1276, Generic Type Smoke-/ Aerosol generator, Subtype: PYROTECHNIC FIRE-FIGHTING DEVICE; CAT P1
Maus Stixx Pro, Registration no. 0589-P1-1277, Generic Type Smoke-/ Aerosol generator, Subtype: PYROTECHNIC FIRE-FIGHTING DEVICE; CAT P1

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