

BEKA associates Ltd.

Ex AUDIT REPORT

SCOPE OF WORKs

QAN\QAR

REPORT NUMBER

103347993LHD-001

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IECEX QAR Reference No.: GB/ITS/QAR06.0002-06
ATEX QAN Number: ITS09ATEXQ6173-06
Free Reference / Project Number: G103347993

Manufacturer : BEKA associates Ltd.
Include Address with post code Old Charlton Rd, Hitchin
Herts. SG5 2DA

Production Site(s) audited : BEKA associates Ltd.
Include Address with post code Old Charlton Rd, Hitchin
Herts. SG5 2DA

Product Description : Communication and telemetry equipment (alarm sounders and
loudspeakers) Instrumentation, measurement and control
equipment.
Luminaires, lamps & accessories.
Signalling & detection products in types of protection.

Number of Employees : Total: 35 No. involved in Ex products: 35

Scope of Audit : Initial Assessment
 Re-Assessment
 Surveillance Assessment

List all applicable Ex Certificates : Refer to IECEX Website.

Electrical equipment with type(s) of protection of : is d e m n DIP
Other (*pressurization "p"*)

Audit Team Leader : A M Smart

Audit Date : 20th February 2018

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 4. Observations
- Appendix A: ISO 9001 Certificate

Intertek Testing and Certification Ltd.
Cleeve Road
Leatherhead
Surrey
KT22 7SA, UK

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SECTION 1
SUMMARY REPORT

Assessment Summary and Conclusions:

(State the most important results and conclusions of the quality assessment)

The quality management system at BEKA associates Ltd. appears to function in a manner acceptable for the ongoing production of ATEX and IECEx certified product. Three observations have been made, which will be reviewed at the next audit.

The quality management system at BEKA has been updated to address the 2015 edition of ISO 9001. However, due to unforeseen circumstances, the audit of the system to ISO 9001:2015 by Bureau Veritas has had to be delayed. It was decided to audit for ATEX / IECEx against the draft 2nd edition of ISO/IEC 80079-34 as the system had been written to address the new edition. Reliance is placed on the existing ISO 9001:2008 certification for compliance with relevant ISO 9001 requirements.

Proposed Recommendation:

An ATEX QAN and IECEx QAR to be maintained for the next 18 months.

As the ISO 9001 certification will be accredited to the 2015 Edition before the next audit is due, please forward a copy of the new certification to Intertek as it becomes available.

Next Quality Audit due : Surveillance October 2019
 Reassessment due February 2021

Non-Conformities

(Indicate the Serial No.(s) of non-conformities recorded. Individual non-conformities are recorded on the non-conformity reports)

NCR 1	None
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Audit Team Leader Recommendations

(Delete where not applicable)

- Certification to be issued/maintained** once satisfactory technical assessment of the product is completed and a test report is issued
- Certification to be issued/maintained*** 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/maintained* 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



A M Smart

Audit Team Leader

05/03/2018



A T Austin

Certification Officer

*Sign to accept Audit Team Leader
recommendations and QAR*

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SECTION 2
AUDIT INFORMATION

2.1 Scope of Audit:

- Type A initial assessment/ reassessment of manufacturer with a certified QMS*.....
- Type B initial assessment/ reassessment of manufacturer without a certified QMS.....
- Type C surveillance of manufacturer with a certified QMS*.....
- Type D surveillance of manufacturer without a certified QMS.....

* where manufacturer has a certified quality system, include certification/registration body, date of registration, certificate No. and scope or append a copy of the certificate (including scope)

See annex A

2.2 Audit Criteria

List any other reference documents, against which Audit was conducted in addition to EN ISO/IEC 80079-34 2011 Ed. 1

- : IECEx OD025: Edition 3.0
- : ISO 9001: 2015
- : Draft Standard ISO/IEC DIS 80079-34:2017

2.3 Date(s) and Duration of Audit

Include total number of auditor days on site

- : 20th February 2018 (1 Day)

2.4 Composition of Audit Team:

NAME	POSITION	ROLE IN AUDIT <i>(SOLE AUDITOR, TEAM LEADER, AUDITOR, TECHNICAL SPECIALIST, ETC)</i>
A M Smart	Senior Consulatnt Engineer	Sole Auditor

2.5 Interviewed Representatives of Manufacturer (Auditee):

NAME	POSITION
Mervyn Wilson	Quality Manager
Chris Burkitt	Director
Steve Riley	Test Manager / Service Manager
Annette Comparetto	Goods-in Inspector / Stores
Mary Revell	Purchasing
Mick Marshall	Production and Engineering manager
Sally Tookey	Production Planner
Ben Brough	Managing Director

2.6 Critical Suppliers: *(List critical suppliers reviewed during audit of supplier evaluation)*

NAME OF SUPPLIER	CRITICAL ITEM OR SERVICE PROVIDED
Wickford Mould and Tool Ltd.	Plastic Enclosure mouldings
Photomechanical Services Ltd.	Printed Circuit Boards (bare)
East Manufacturing Tech. Ltd.	Transformers

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SECTION 3

DOCUMENTATION REVIEW AND ASSESSMENT OF IMPLEMENTATION

(For surveillance audits, major document changes only may be reviewed)

DRAFT STANDARD ISO/IEC DIS 80079-34:2017 CLAUSES		ASSESSED (Y, N OR N/A)	MANUFACTURER'S DOC. REF. LIST DOCUMENT(S) VIEWED, WITH REVISION STATUS, AND COMMENTS LIST ANY PERTINENT DETAILS / COMPLIANCE WITH REQUIREMENTS OF CLAUSE	NCR REF.
4.	Context of Organisation			
4.1	Understanding the organisation and its context	Y	New quality manual to address ISO 9001:2015 QS1 – Quality Manual at Issue 1 30/10/2017 Approved by B Brough (Ben) – The Managing Director. QS2 – Policies QS3 – Health and safety	
4.2	Understanding the needs and expectations of interested parties	Y	Ex products / ATEX / IECEx / 80079-34 requirements are identified in the section 1.4.3 – determining the scope of the quality management system. 80079-34 is noted as a reference document and states that this is considered to take higher priority over 9001.	
4.3	Determining the scope of the quality management system	Y	See 4.2	
4.4	Quality management system and its processes	Y	See 4.2 There are Ex and non-Ex products, but all product is made as if it were an Ex product, only the label is different.	
5.	Leadership			
5.1.1	General	Y	ISO 9001 Cert / Quality Manual	
5.1.2	Customer focus	Y	ISO 9001 Cert / Quality Manual	
5.2.1	Establish the Quality Policy	Y	ISO 9001 Cert / Quality Manual	
5.2.2	Communicating the Quality Policy	Y	ISO 9001 Cert / Quality Manual	

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5.3	Organisational roles, responsibilities and authorities	Y	<p>Roles for the authorized person are defined in the quality manual section 1.5.3</p> <p>The "family tree" defines Chis Burkitt as the authorized person.</p> <p>Deputies are defined for the role. At present, only the Principal Engineer (Olivier Lebreton) is present. There is no Technical Director or Certification Engineer.</p> <p>Concessions are covered under 8.2.1 and defines that the authorized person must be satisfied that the concession is acceptable.</p> <p>Authorization of drawing changes by the authorized person defined in OP-11 Rev 2 – Document Change.</p> <p>Control of sales literature in OP-1 section 1.8. Authorized Person endures that any special conditions and schedule of limitations is conveyed to the user in the instructions.</p> <p>The Authorized person is defined as having responsibilities for all certified product, but the present wording does not fully cover point (g).</p> <p>Records are kept, such as concession notes, drawing approvals and the quality system management review.</p>	OBS 1
6.	Planning			
6.1	Actions to address risks and opportunities	Y	ISO 9001 Cert / Quality Manual	
6.2	Quality objectives and planning to achieve them	Y	ISO 9001 Cert / Quality Manual	
6.3	Planning of changes	Y	ISO 9001 Cert / Quality Manual	
7.	Support			
7.1.1	General	Y	ISO 9001 Cert / Quality Manual	
7.1.2	People	Y	ISO 9001 Cert / Quality Manual	
7.1.3	Infrastructure	Y	ISO 9001 Cert / Quality Manual	

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7.1.4	Environment for the operation of processes	Y	ISO 9001 Cert / Quality Manual	
7.1.5	Monitoring and measuring resources	Y	Calibration QS1 section 1.7.1 resources, mentions monitor and measuring resources mentions that calibration is traceable to national standards OP7 Inspection – Issue 18, 30/10/2017 Section 7.10 External calibrations are made by a UKAS approved calibration service. Internal calibrations are made using an externally calibrated master gauge.	
7.1.6	Organisational knowledge	Y	Calibration record sheet (QF18)	
7.2	Competence	Y	ISO 9001 Cert / Quality Manual QS1 section 1.7.2 Competence OP9 – Training procedure Rev 7 30/10/2017 Training records maintained by Finance Director (with employment etc.). Skills matrix on shop floor for assembly staff.	
7.3	Awareness	Y	ISO 9001 Cert / Quality Manual	
7.4	Communication	Y	QS1 Section 1.7.4 Communication All published documentation is controlled via the document control procedure OP 11 All information is available by the company website.	
7.5	Documented Information			
7.5.1	General	Y	Documented information in QS1 section 1.7.5. Controlled via the manufacturing information system, with the input data for that controlled by the Principal Engineer. The information is defined during the certification process.	
7.5.2	Creating and updating	Y	ISO 9001 Cert / Quality Manual	

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7.5.3	Control and documented information	Y	<p>OP1 Issue 18, Section 1.5</p> <p>Addresses the requirements a, b, c, d, e, f, g, h,</p> <p>The certification register lists all certificates and the QAN / QAR certificates, but there is no direct link as required by 7.5.3 (g)</p> <p>The annual review is covered as part of the management review. One of the input items.</p> <p>QS1 section 1.9.3 management review inputs.</p> <p>List of records kept is defined in OP1 section 1.7, Quality Records</p> <p>10 year retention period is specified.</p>	OBS 2
8	Operation			
8.1	Operational planning and control	Y	<p>Production has works instructions and build procedures and test procedures, all controlled under the document control system. (OP1 section 1.4)</p>	
8.2.1	Customer communication	Y	<p>ISO 9001 Cert / Quality Manual</p>	
8.2.2	Determining the requirements for the products and services	Y	<p>ISO 9001 Cert / Quality Manual</p>	
8.2.3	Review of the requirements for the products and services	Y	<p>QS1 section 1.8.2</p> <p>The certification details are conveyed via the company's data sheets and the catalogue online.</p> <p>There is a review that the certification requirements / customer requirements are met. Amendments are subject to the same level of review.</p> <p>OP2 Issue 19 Order processing</p> <p>The order acknowledgement includes the certification details, this is defined in the manufacturing information system.</p> <p>This information is controlled, see 7.4</p>	

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8.2.4	Changes to requirements for products and services	Y	Covered under change management OP11	
8.3	Design and Development of products and services			
8.3.1-		N/A		
8.3.5				
8.3.6	Design and development changes	Y	OP11 Document Change procedure. See 7.5.3	
8.4	Control of externally provided processes products and services			
8.4.1	General	Y	1.8.4 control of externally provided processes. Responsibility remains with the company regardless of any subcontracted operations. OP 3 Purchasing Supplier approvals under 3.3 Covers (b)(d)(f)(g) Not 100% inspection. Inspection is defined according to the drawings. Goods receiving is on a sample basis. PCBs are 100% AOI inspected. Components are provided by BEKA and the sub-supplier is not permitted to use their own local components. Components are recoded in the pick and place reel change logs to prove that the BEKA supplied component have been used. Every board is AOI inspected at BEKA to ensure the correct components are fitted. Encapsulation is done in house. No external process that cannot be inspected. PCBs rely on CofC from the supplier. The board manufacturer is specified by BEKA.	

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8.4.2	Type and extent of control	Y	Covered under 3.3 Routine tests are done in house. (flash-test) Transformers rely on the CofC from the supplier where the transformer is a bought in item. Transformers assembled as part of the assembly process are tested in house. There are no external processes that cannot be verified in house. On PCB's the CTI value is specified on the drawings, and the C of C will specify conformity with the drawing.	
8.4.3	Information for external providers	Y	OP 3 Issue 16 - Purchasing procedure section 3.2 Drawings / rev status are specified on the PO, and the supplier must request the drawing if they do not have it. Amendments to the POs are appropriately marked with a revision and controlled as with the original. The procedure under OP3 is not in agreement with 8.4.3 (d) or the stated practice with purchasing (see above)	OBS 3
8.5	Production and service provision			
8.5.1	Control of production and service provision	Y	OS1 – section 1.8.5	
8.5.2	Identification and traceability	Y	Verified as part of the vertical audit. OS1 – section 1.8.5 Traceability is maintained on finished product and sub-assemblies. Tracking to component level is on a date basis only.	
8.5.3	Property belonging to customers or external providers	Y	OS1 – section 1.8.5 Concerning repair of Ex product, items are labelled.	
8.5.4	Preservation	N/A	ISO 9001 Cert / Quality Manual	
8.5.5	Post-delivery activities	N/A	ISO 9001 Cert / Quality Manual	

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8.5.6	Control of changes	Y	Covered by OP11 – Change control. Changes to production are authorized by the authorized person. QS1 section 1.8.5	
8.6	Release of products and services	Y	Routine tests are conducted in house. All products have to go through testing prior to dispatch. OP6 – Factory Operations. Issue 19 Under “Final Calibration”	
8.7	Control of non-conforming product	Y	Provision of instruction under “Preservation” in QS1 section 1.8.5. QS1 section 1.8.7 OP8 Issue 27 8.2 – control of nonconforming products. 8.2.5 – Despatched Product addresses product recall and items (c) to (g) Concessions – OP8, 8.2.1 - concessions for the product that take it outside the design, as defined in the Ex certificate and technical documentation, are not permitted.	
9	Performance Evaluation			
9.1	Monitoring, measurement, analysis and evaluation			
9.1.1	General	Y	ISO 9001 Cert / Quality Manual	
9.1.2	Customer satisfaction	Y	ISO 9001 Cert / Quality Manual	
9.1.3	Analysis and evaluation	Y	ISO 9001 Cert / Quality Manual	

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9.2	Internal audit	Y	<p>QS1 section 1.9.2</p> <p>Audit program is specified as being at least once per year.</p> <p>OP8 section 8.3 Internal Audit</p> <p>Vertical audits are used in addition to internal audits against the QMS.</p> <p>The internal audit plan is in place for 2018 Scheduled for February to December.</p> <p>At present, an audit is done against a procedure, rather than being process orientated.</p> <p>Vertical audits are based on ordering a product for production or using a production piece destined for a customer.</p>	
9.3	Management review			
9.3.1	General	Y	<p>1.9.3 management review.</p> <p>Defines the review inputs and addresses the Ex requirements and review of certificates.</p> <p>The authorized person attends.</p> <p>Last meeting 23rd Feb 2017</p> <p>Next meeting scheduled for 8th March 2018</p>	
9.3.2	Management review inputs	Y	ISO 9001 Cert / Quality Manual	
9.3.3	Management review outputs	Y	ISO 9001 Cert / Quality Manual	
10	Improvement			
10.1	General	Y	ISO 9001 Cert / Quality Manual	
10.2	Non-conformity and corrective action	Y	ISO 9001 Cert / Quality Manual	
10.3	Continual improvement	Y	ISO 9001 Cert / Quality Manual	
Annex A: Information relevant to particular types of protection				
A.1	General	Y	Work instructions available	
A.2	General - Material composition of (parts of)	Y	C of C from moulding supplier lists	

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enclosures		materials used.	
A.3 Ex d - flameproof enclosures			
A.3.1 Verification	N/A	Bought-in certified components are used	
A.3.2 Castings	N/A		
A.3.3 Machining	N/A		
A.3.4 Cemented joints and potted assemblies	N/A		
A.3.5 Routine pressure testing	N/A		
A.3.6 Flanged joints	N/A		
A.3.7 Sintered components	N/A		
A.4 Ex i - intrinsic safety			
A.4.1 Components for intrinsically safe products	Y	Work instructions available	
A.4.2 Printed circuit boards (PCB)	Y	The use of work instructions and quality control	
A.4.2.1 Non-populated PCB's	Y	Use of work instructions	
A.4.2.2 Populated PCB's	Y	Use of work instructions	
A.4.3 Sub-assemblies and assemblies	Y	PCBs are held as sub assemblies and the final product built / configured to order, according to works order.	
A.4.4 Tests	Y	Dielectric Strength tests done and recorded.	
A.4.5 Intrinsically safe circuits and assemblies housed in Ex d, Ex p or Ex q enclosures	N/A		
A.5 Ex e – increased safety and nA Non Sparking			
A.5.1 Ingress protection	Y	Procedures endure the enclosure seals and gaskets are correctly installed.	
A.5.2 Internal wiring and contact integrity	Y	Assembly procedures are provided. All pluggable connections.	
A.5.3 Rotating machines	N/A		
A.5.4 Windings	N/A		
A.5.5 Terminal Boxes	N/A		
A.5.6 Cable glands, terminals and other accessories	N/A		
A.5.5 Routine verification and tests	Y	Dielectric Strength tests done and recorded.	
	N/A		
A.6 Ex p – pressured apparatus			
A.6.1 Ingress protection	Y	The enclosure is approved as suitable for “p” as a component based on also being a “e” component. See above.	
A.6.2 Components and manufacturing process	N/A		
A.6.3 Components, constructional characteristics	N/A		
A.6.2 Routine verification and tests	N/A		
A.7 Ex m – encapsulation			
A.7.1 Production documentation	N/A		

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A.7.2	Routine verification and tests	N/A		
A.8 Ex o – oil immersion				
-	Routine verification and tests	N/A		
A.9 Ex q – powder filling				
A.9.1	Material control	N/A		
A.9.2	Filling	N/A		
A.9.3	Ingress protection	N/A		
A.9.4	Routine verification and Tests	N/A		
A.10 Ex t – Dust ignition protection by enclosure				
A.10.1	Casting	N/A		
A.10.2	Enclosure parts	Y	As for "e" / "nA"	
A.10.3	Gaskets	N/A		
A.10.4	Protection devices	N/A		
A.10.5	Cemented and cast enclosure parts	Y	As for "e" / "nA"	
A.10.6	Ingress protection	Y	As for "e" / "nA"	
A.10.7	Examinations			
A.11 Gas Detectors				
--	Performance checks	N/A		
A.12 Flame arresters				
--	Measurement and testing	N/A		

Section concerning Annex for non-electrical equipment and sintered components deleted, as there is no relevant production..

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SECTION 4

OBSERVATIONS

Additional assessor notes, Summary of audit trail (e.g. Who? What? Where? When? etc.) (Could be positive, negative, improvement, etc). Include brief comments on each department/function audited.

OBSERVATION 1

5.3 Organisational roles, responsibilities and authorities

g) the effective coordination of manufacturing processes related to Ex Products including externally provided products, services and processes detailed in 8.4; In the case of a manufacturer with multiple manufacturing sites an Ex authorized person with relevant responsibilities shall be appointed for each site.

The Authorized Person is defined as having responsibilities for all certified product, but the present wording does not fully cover point (g).

OBSERVATION 2

7.5.3 Control and documented information

g) the manufacturer shall document who is responsible for the quality system of each Ex certificate.

The certification register lists all certificates and the QAN / QAR certificates, and the Declaration of

Conformity lists both the product certificate number and the QAN provider and Notified Body number,

but there is no direct link as required by 7.5.3 (g)

OBSERVATION 3

8.4.3 Information for external providers

d) where the manufacturer does not provide such documents with subsequent orders, then the manufacturer shall have procedures for ensuring that suppliers have current copies of documents and that their integrity be maintained

Amendments to the Purchase Orders are appropriately marked with a revision and controlled as with the original. The procedure under OP3 is not in agreement with 8.4.3 (d) or the stated practice with purchasing.

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APPENDIX A
ISO 9001 CERTIFICATE

