

**INTERNATIONAL ELECTROTECHNICAL COMMISSION SCHEME FOR CERTIFICATION TO
STANDARDS FOR EXPLOSIVE ATMOSPHERES (IECEX SCHEME)**

Ex Management Committee, ExMC

**TITLE: IECEX Assessment Report for acceptance of “KEMA Quality BV” as an Ex
Certification Body**

This document contains the IECEX Assessment Report for the acceptance of “KEMA Quality BV” of The Netherlands as an Ex Certification Body (ExCB) within the IECEX Scheme.

The report is hereby submitted for voting

Please consider the assessment report and return the completed voting form to the Secretariat by **2005 03 10**. Your speedy response to the voting process will be very much appreciated.

You may return your completed voting form (available in Word format) via fax or e-mail. Details below.

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Voting Form

IECEX Assessment Report for acceptance of the following candidate as an
Ex Certification Body

KEMA Quality BV of Netherlands

- Yes. I agree with the acceptance of **"KEMA Quality BV"** as an
Ex Certification Body (ExCB)
- No. I do not agree with the acceptance of **"KEMA Quality BV"** as an
Ex Certification Body (ExCB) within the IECEX Scheme, for the following reasons

Signature: _____

Name: _____

Member Body: _____

Date: _____

Please complete and return by **2005 3 10** to:

Mr Chris Agius
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IECEX ASSESSMENT REPORT FORM

For ExCB

(Accepted Ex Certification Body)

Type of Assessment:

Initial Assessment for Candidate ExCB
~~Surveillance Assessment for existing ExCB~~

1. OBJECT AND FIELD OF APPLICATION

1.1 *Country:*

The Netherlands

1.2 *Name of Candidate ExCB*

KEMA Quality BV

1.3 *Members of the Assessment Team*

Mr C. Agius

Mr W. Dunn

Mr V. Varma

1.4 *Place And Date Of Assessment*

Utrechtseweg 310

6812 AR Arnhem, The Netherlands

MTSA

Arnhem, The Netheralnds

Site Assessors:

Mr C. Agius- Lead Assessor

Mr V. Varma

Following a review of all documentation submitted, a site assessment was conducted on 9, 10 and 11 November 2004. The site assessment was conducted by two assessment team members and included both the KEMA Quality BV and MTSA sites. The site visit included a review and completion of the IECEX ISO/IEC Guide Checklist (OD 007) , now retained on file by the IECEX Secretariat. During the 9, 10 and 11 November 2004 visit, some issues were raised largely concerning the procedures and documentation. Improvements made by KEMA, including revision of procedures and documentation, were reviewed at a follow up visit on 6 and 7 December 2004 and these were found to be satisfactory. All items raised and recorded in the ISO/IEC Guide 65 Checklist have now been successfully closed by the Assessment Team, with full records of both the initial and follow up visits retained on file by the IECEX Secretariat.

1.5 **Assessment References**

Document:

- i) IECEx 02 Second Edition
- ii) IECEx Operational Document OD/003
- iii) ISO/IEC Guide 65 1996
- iv) ExCB application documents

1.6 **Scope Of Application**

Product Category	Standard
General Requirements	IEC 60079-0
Flameproof Enclosures	IEC 60079-1
Pressurised enclosures	IEC 60079-2
Powder Filling	IEC 60079-5
Oil Immersion	IEC 60079-6
Intrinsic safety	IEC 60079-11
Increased Safety	IEC 60079-7
Encapsulation	IEC 60079-18
Non Sparking	IEC 60079-15
Dusts	IEC 61241 series

During the site assessment visit of 9, 10 and 11 November 04 and at the request of KEMA Quality BV, the Lead Assessor noted the current certification service that KEMA Quality BV provide regarding the assessment and certification of Ex Repair Workshops and determined that KEMA Quality BV are in a very good position to seek an extension of scope to cover this area once it is available by the IECEx Scheme.

1.7 **Candidate ExCB Persons Interviewed**

<u>Name</u>	<u>Position</u>
Theo Pijpker	Technical Manager, Hazardous Locations
Arthur van der Meijden	Manager Operations
Mark Hikspoors	Manager Industrial
Mr Jan Spee	Quality Manager
Mr Bert Vries	Certification Manager
Carla Everhard	Legal Department

In addition to the above there were many others interviewed from various departments such as:

- Purchasing
- Quality
- Personnel
- Corporate

1.8 **Legal Entity Of The Candidate ExCB**

KEMA Quality BV is a limited liability Company organised under the laws of the Netherlands. The legal documentation was verified during the site assessment visit.

1.9 **Associated Testing Laboratories**

Names of Laboratories

Address

KEMA Quality BV has an integral Laboratory located at the same address

The Assessment Team are satisfied that a clear separation exists between testing and Certification as required by ISO/IEC Guide 65.

1.10 **Associated Certification Functions**

KEMA Quality BV are involved in various other Certification activities including:

- IEC CB Scheme
- ATEX Directive
- Medical Devices Directive
- EMC Directive
- Low Voltage Directive
- Machinery Directive
- Operating as agent for various national certification bodies, including CSA and FM

1.11 **National Marks And Certificates**

KEMA Quality BV issue the KEMA-KEUR Mark for local requirements

1.12 **Financial Support**

KEMA Quality BV derives its funding from the charges for its services. As part of the assessment the Assessment Team confirmed that there are sufficient financial resources for KEMA Quality BV to meet its obligations

1.13 **History**

N.V. KEMA was founded in 1927 as the Dutch electricity industry's test house. KEMA Quality BV is a business unit of the N.V. KEMA, with testing and certification of household, commercial and industrial products and components as its core business. In the 1960's KEMA already tested and certified Ex-products for national use. Since 1991 KEMA Quality B.V. as an Ex Notified Body assesses and certifies Ex-products according to the European Directives

1.14 **Standards Accepted**

KEMA Quality BV operates within the European CENELEC system and as such declares compliance with the declared European Group differences and standards listed in the IECEx Bulletin.

1.15 **National Differences To IEC Standards**

See 1.14 above

2. ORGANISATION

2.1 Names, Titles And Experience Of The Senior Executives

Name	Title	Experience
Mr Erik Duim	Managing Director	5 years
Mr Martin Van der Dussen	Vice President	17 years
Mr Mark Hikspoors	Manager Team Industrial	9 years
Mr Arhtur van der Meijden	Operational Manager Team Industrial	10 years
Mr Theo Pijpker	Technical Manager Ex-group	15 years

2.2 Name, Title and Experience of the Quality Management Representative

Name	Title	Experience
Mr Jan Spee	Quality Manager	26 years

2.3 Name and Title of Nominated Principal Contact

Name	Title	Comments
Mr Theo Pijpker	Ex Product Expert / Technical Manager	
Mr Bert Vries	Certification Manager	

2.4 Name and Title of Signatories for Certification

Name	Title	Comments
Mr Theo Pijpker	Ex Product Expert / Technical Manager	

2.5 Other Employees in ExCB activity

Name	Title	Responsibility
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Refer to Organisation Chart in Annex A

2.6 Organisational Structure

In referring to the organisational structure, the IECEX Assessment Team determined that the structure provides for sufficient and competent resources to fulfil the requirements in delivering IECEX Certification services in a timely and efficient manner.

The structure also provides for the necessary independence between testing and certification decisions with appropriate reviews of evaluations as required by Guide 65.

2.7 Administration

2.7.1 Administrative Structure

Testing is conducted separate to the Certification activities. The assessment and audit of manufacturers is performed by a KEMA qualified IECEx auditors.

The Assessment Team also concluded that the related IECEx Operational Documents were integrated into the KEMA system to ensure that they are applied in full when processing IECEx applications.

2.7.2 Terms of Reference of the Governing Board

KEMA Quality BV operate under the direction of their Board of Directors whom oversee and approve policies

3. RESOURCES

(Verification that ACB has all necessary resources for its operation in-house, including personnel trained and experienced in factory inspection / quality audits).

The site assessment revealed adequate resources, personnel and facilities, in order to meet the requirements of the IECEx Scheme for the issuing of ExTRs, IECEx QARs and IECEx Certificates of Conformity. A very high level of competence in the certification of Ex equipment and systems was demonstrated by all levels of the KEMA Management and Staff. The Assessment Team were also confident in the knowledge and experience of KEMA approved auditors to conduct IECEx audits to IECEx OD 005.

The KEMA Quality BV Ex Department comprises a total of 19 Technical staff.

4. COMMITTEES

KEMA Quality BV are participants in committees at both the national and internal level as well as being active members of the ExTAG and ExMC Committees

5. CERTIFICATION OPERATIONS

5.1 *National Approval/Certification Methods*

The KEMA Quality BV certification operations were reviewed in detail by the assessment team during the site assessment visit on 9, 10 and 11 November 04. While the site visit revealed general compliance with ISO/IEC Guide 65 and IECEx requirements, a number of items were raised during the site assessment visit, related to a need to amend various quality system documentation in order to address the specific requirements and operations of the IECEx Scheme.

A revised set of documentation was prepared and submitted to the assessment team with a review being conducted as well as a follow up site assessment visit being conducted on 6 + 7 December 2004.

The Assessment team now concludes that the changes made to the documentation mean that all requirements of IECEx are now fulfilled.

5.2 Certification Policy

This is included in the Quality Manual and was noted during the 9, 10, 11 November assessment visit

5.3 Staff Work Instructions

There are an effective and comprehensive set of work instructions incorporated within the KEMA Quality BV system.

5.4 Application for Certification

During the 9, 10, 11 November assessment visit the assessment Team determined that the KEMA Quality procedures are non discriminatory.

6. STATISTICS

Certificates issued during the past 2 years:

flameproof	d	166
intrinsic safety	i	202
increased safety	e	75
powder filled	q	6
oil immersion	o	2
encapsulated	m	56
type	n	36
pressurised	p	23
Apparatus for Dusts		42

7. DOCUMENTATION

Document and Change Control

The KEMA Quality BV Quality System provides for a very effective system of control over document changes and authorisation, utilising the KEMA Quality internal computer system.

8. RECORDS

KEMA Quality BV have amended their procedures to ensure that all records related to IECEx activities are maintained for a minimum period of 10 years. The assessment team examined the system for retaining records and also the recollection of data and were satisfied that the requirements of Guide 65 and IECEx were met.

9. CONFIDENTIALITY

The KEMA Quality BV management system ensures that all staff and any contractors sign a confidentiality agreement which also addresses "conflict of interest". During the November 2004 initial site visit the assessment team checked a sample of records for both senior managers and Ex staff and found that copies of such agreements were in place. The Assessment further reviewed publicly available documentation and were satisfied that the requirements of both ISO/IEC Guide 65 and IECEx requirements were met.

10. PUBLICATIONS

KEMA Quality BV have published a number of papers relating to the Ex field including:

- a guidance paper how to deal with the ATEX directive
- how to deal with Ex d cable glands (related to the flow chart in IEC 60079-14)
- how to use Safety Integrity Levels (SIL) in the control system for Ex p panels, based on EN 954 and IEC 61508 / 61511

In addition KEMA Quality BV participate and run various workshops on Ex such as ATEX.

11. APPEALS

The KEMA Quality BV management system includes an appeals mechanism which has been expanded to include reference to the IECEx appeals process.

12. NATIONAL ACCREDITATION

While KEMA Quality BV hold accreditation to ISO/IEC Guide 65 for various aspects of their certification business, the scope currently does not cover the Ex activities and therefore, at this stage the assessment team recommends annual surveillance of the ExCB functions by IECEx.

13. RECOGNITION AND AGREEMENTS

KEMA Quality BV agreements and recognitions include

- Notified Body under ATEX
- IECEE CB Scheme
- CSA
- FM

14. QUALITY MANUAL

KEMA Quality BV maintains a full and comprehensive Quality Manual which is on-line for all staff to access. This was reviewed by the assessment team and found to fully meet the requirements of ISO Guide 65

15. INTERNAL AUDIT AND PERIODIC REVIEW

KEMA Quality BV operate a very sound and well controlled Internal audit program with results being raised at Management reviews. This internal audit system has been expanded to also cover specific IECEx requirements and operational procedures, including a stronger technical focus on Ex activities.

16. COMPLAINTS

The existing Complaints system operated by KEMA Quality BV has been expanded to capture all possible complaints relating to IECEx services.

17. WITHDRAWAL AND CANCELLATION OF CERTIFICATES

The KEMA Quality BV procedures cover the cancellation or withdrawal of Certification and with the existing procedures being expanded to clarify the procedure of withdrawing or cancelling certificates arising from possible errors from KEMA. The Assessment Team is satisfied that all IECEx requirements have been met.

18. SPECIAL FACTS TO BE NOTED

In noting that the scope of KEMA Quality BV RvA accreditation to ISO/IEC Guide 65 does not currently cover Ex activities, the IECEx assessment team recommend annual surveillance visits in accordance with IECEx rules.

19. RECOMMENDATION

With the successful completion of the two site assessments:

- 9, 10 and 11 November 2004 (Initial Visit)
- 6 + 7 December 2004 (Follow up visit)

The IECEx assessment Team hereby recommend full acceptance of KEMA Quality BV as an IECEx Certification Body for the scope specified in 1.6.

Chris Agius
Team Leader

Mr Vijay Varma

Mr Bill Dunn

LIST OF ANNEXES

Annex A Organisation Chart

Annex A

Organisation chart Ex-group (status November 1, 2004)

