

**INTERNATIONAL ELECTROTECHNICAL COMMISSION SYSTEM FOR  
CERTIFICATION TO STANDARDS RELATING TO EQUIPMENT FOR USE  
IN EXPLOSIVE ATMOSPHERES (IECEx SYSTEM)**

**Title: Re-assessment Report for the continued acceptance of KEMA Quality  
B.V. as an Accepted Certification Body (ExCB).**

**To: Members of the IECEx Management Committee, ExMC**

---

**Introduction**

In accordance with the 5 year re-assessment plan for the surveillance and monitoring of bodies within the IECEx System, this document contains the IECEx Re-assessment Report for KEMA Quality B.V, an Accepted ExCB.

This Report is issued for endorsement during the 2011 ExMC Split Meeting.

It should be noted that from 2011 01 01 KEMA Quality will be known as DEKRA Certification B.V.

*Chris Agius*

**IECEx Secretariat**

<p><b>IECEx Secretariat Standards Australia Building 286 Sussex Street Sydney NSW 2000 Australia</b></p>	<p><b>Tel: +61 2 8206 6940 Fax: +61 2 8206 6272 Email: <a href="mailto:chris.agius@iecex.com">chris.agius@iecex.com</a></b></p>
--	---

# IECEX ASSESSMENT REPORT FOR KEMA Quality B.V. ExCB (IECEX 02 Certification Body)

**Type of Assessment: (please mark)**

**Initial Assessment for Candidate ExCB**

**Re-Assessment of ExCB** **X**

**Scope Extension of ExCB** **X**

## 1. OBJECT AND FIELD OF APPLICATION

### **1.1. Country:**

The Netherlands

### **1.2. Name of Candidate ExCB**

KEMA Quality B.V.

### **1.3. Members of the Assessment Team**

Mr. Jim Munro, IECEx Lead assessor

Mr. Vijay Varma, IECEx Expert assessor

### **1.4. Place and Date of Assessment**

Place: Utrechtseweg 310, 6812 AR Arnhem, The Netherlands

Date: 24-26 March, 2010 (6 man-days)

### **1.5. Assessment References**

- i) IECEx 02 Third Edition 2006-11 IECEx Scheme rules of procedure
- ii) IECEx OD 003 V1 IECEx Assessment procedures
- iii) IECEx OD 005 V2 Quality System requirements for manufacturers
- iv) IECEx OD 009 V1 Issuing of CoCs, ExTRs and QARs
- v) IECEx Document OD 025 V1 (ExMC/161/CD) Management of assessment and surveillance programs for manufacturers (includes QAR forms)
- vi) ISO/IEC Guide 65:1996
- vii) IECEx Document OD 17 Drawing and documentation guidance

### **1.6. Scope of Application**

Number	Title
60079-0 Edition 5	Explosive atmospheres - Part 0: Equipment - General requirements
60079-1 Edition 6	Explosive atmospheres - Part 1: Equipment protection by flameproof enclosures "d"
60079-2 Edition 5	Explosive atmospheres - Part 2: Equipment protection by pressurized enclosure "p"

Number	Title
60079-5 Edition 3	Explosive atmospheres - Part 5: Equipment protection by powder filling "q"
60079-6 Edition 3	Explosive atmospheres - Part 6: Equipment protection by oil immersion "o"
60079-7 Edition 4	Explosive atmospheres - Part 7: Equipment protection by increased safety "e"
60079-11 Edition 5	Explosive atmospheres - Part 11: Equipment protection by intrinsic safety "i"
60079-15 Edition 3	Electrical apparatus for explosive gas atmospheres - Part 15: Construction, test and marking of type of protection "n" electrical apparatus
60079-18 Edition 3	Electrical apparatus for explosive gas atmospheres - Part 18: Construction, test and marking of type of protection encapsulation "m" electrical apparatus
60079-25 Edition 2	Electrical apparatus for explosive gas atmospheres - Part 25: Intrinsically safe systems
60079-26 Edition 2	Explosive atmospheres - Part 26: Equipment with equipment protection level (EPL) Ga
60079-27 Edition 2	Explosive atmospheres – Part 27: Fieldbus intrinsically safe concept (FISCO)
60079-28 Edition 1	Explosive atmospheres - Part 28: Protection of equipment and transmission systems using optical radiation ( <b>extension of scope</b> )
60079-30-1 Edition 1	Explosive atmospheres – Part 30-1: Electrical resistance trace heating – General and testing requirements
60079-31 Edition 1	Explosive atmospheres – Part 31: Equipment dust ignition protection by enclosure "t"
61241-0 Edition 1	Electrical apparatus for use in the presence of combustible dust - Part 0: General requirements
61241-1	Electrical apparatus for use in the presence of combustible dust - Part 1: Protection by enclosures 'tD'
61241-1-1	Electrical apparatus for use in the presence of combustible dust - Part 1: Electrical apparatus protected by enclosures and surface temperature limitation - Specification for apparatus
61241-4 Edition 1	Electrical apparatus for use in the presence of combustible dust Part 4: Protection by enclosures "tD" plus -1
61241-11 Edition 1	Electrical apparatus for use in the presence of combustible dust – Part 11: Protection by intrinsic safety 'iD'
61241-18 Edition 1	Electrical apparatus for use in the presence of combustible dust Part 18: Protection by encapsulation "mD"
62013-1 Edition 2	Caplights for use in mines susceptible to firedamp Part 1: General requirements - Construction and testing in relation to the risk of explosion

Number	Title
62086-1	IEC 62086-1 Part 1: Electrical apparatus for explosive gas atmospheres Electrical resistance trace heating – Part 1: General and testing requirements

### 1.7. Candidate ExCB Persons Interviewed

Name	Position
Mr Arthur van der Meijden	Team / Business Line Manager EX
Mr. Erik Folgering	Operational Manager EX
Mr. Theo Pijpker	Product Expert / Certification Manager EX
Mrs. Anne-Fré Vollema	Quality & Legal Manager
Mrs. Theresa Kaya	Assistant Quality Manager
Mrs. Carla Everhard	Legal department
Mrs Linda Bouwhuis	Business Support Office
Mr. Richard Schuller	Lead Auditor

*Note: KEMA EX is in the middle of an organization change from Team to Business Line. As a result, some position descriptions may be altered.*

### 1.8. Legal Entity of the Candidate ExCB

KEMA Quality BV is a limited liability company organised under the laws of the Netherlands. Since 1<sup>st</sup> November 2009 KEMA has been part of the DEKRA Group. This is itemised in 2.2 of the Quality Manual. The company shares are now held by DEKRA.

The legal standing of the company was verified during the site assessment visit.

### 1.9. Associated Testing Laboratories

KEMA Quality BV has an integral laboratory located at the same address.

### 1.10. Associated Certification Functions

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

- IECEE CB Scheme
- IECEX 03 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 issues the KEMA-KEUR Mark for local requirements. This will continue under the new ownership.

### 1.12. Financial Support

KEMA Quality BV derives its funding from the charges for its services.

### 1.13. *History*

N.V. KEMA was founded in 1927 as the Dutch electricity industry's test house. KEMA Quality B.V. and was, until 1 November 2009, a business unit of the N.V. KEMA, with testing and certification of household, commercial and industrial products, assessment and certification of Quality Management Systems and Personnel Certification as its core business. From 1<sup>st</sup> November 2009 KEMA Quality B.V. became a member of the DEKRA Group, with unchanged scope and activities. Since 1991 KEMA Quality B.V. as an ATEX Notified Body has assessed and certified Ex-products and Ex-production sites according to the European Directives. In March 2005 KEMA was approved as an IECEx 02 ExCB/ExTL, followed by IECEx 03 ExCB approval in May 2007.

### 1.14. *Standards Accepted*

See clause 1.6 of this report.

### 1.15. *National Differences to IEC Standards*

National differences to IEC standards are listed in the latest version of the IECEx Scheme Bulletin.

## 2. ORGANISATION

### 2.1. *Names, Titles and Experience of the Senior Executives*

Name	Title	Ex Experience (years)
Mr. Bert Zoetbrood	Managing Director	3
Mr. Arthur van der Meijden	BL Manager EX	16
Mr. Erik Folgering	Operational Manager EX	3

See for more details the Organization Chart KEMA Quality Group (February 5, 2010)

### 2.2. *Name, Title and Experience of the Quality Management Representative*

Name	Title	Experience (years)
Mrs. Anne-Fré Vollema	Quality & Legal Manager	24

### 2.3. *Name and Title of Nominated Principal Contact*

Name	Title	Experience (years)
Mr. Theo Pijpker	Product Expert EX	19

### *Name and Title of Signatories for Certification*

Name	Title	Experience (years)
Mr. Theo Pijpker	Certification Manager	19
Mr. Kees van Es	Certification Manager	25

### 2.4. *Other Employees in ExCB activity*

Name	Title	Responsibility and Experience in Ex
Mr. Marco Erdhuizen	Auditor	5 years
Mr. Eric Giusti	Auditor	6 years
Mr. Erwin ter Haar	Auditor	11 years
Mr. Koichi Masuki	Auditor	4 years

Name	Title	Responsibility and Experience in Ex
Mr. Richard Schuller	Auditor	5 years
Mr. Bert Vries	Auditor	22 years

## 2.5. **Organizational Structure**

See Annex 1, KEMA Quality Group, an overview of the organization. The area considered in this assessment is the area entitled 'BL Explosives'.

See Annex 2, Organization Chart for the Ex Business Line to see the staff within the Ex operation.

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.

In principle the structure and procedures also provide for the necessary independence between testing and certification decisions with appropriate reviews of evaluations as required by Guide 65. However, there was an issue raised regarding instances of the same person signing off ExTRs in both an ExTL and ExCB role. Procedures were revised to avoid this occurring in the future and these were reviewed by the assessment team and found to be satisfactory.

## 2.6. **Administration (including Indemnity Insurance)**

There is a public and product liability insurance policy for EUR 100M current to 1 January 2011. Evidence was provided that this policy also covers professional indemnity.

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

The Assessment Team found that the related IECEx Operational Documents were integrated into the KEMA system (on Ex Sharepoint) to ensure that they are applied in full when processing IECEx applications.

KEMA Quality BV operates under the direction of their Board of Directors whom oversees and approves policies.

# 3. RESOURCES

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 CoCs. A 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 was also confident in the knowledge and experience of KEMA approved auditors to conduct IECEx audits to IECEx OD005.

The KEMA Quality B.V. Ex Business Line comprises a total of 21 Technical staff (18 in Arnhem, NL and 3 in Japan).

# 4. COMMITTEES / Governing Board / Appeals / Advisory Board

KEMA has two committees related to certification. The one currently relevant to the IECEx System is the 'Committee of Experts for Product Certification'. This comprises

experts from a range of interests relevant to product certification. The committee meets twice a year and has the power to form an appeals committee if required.

There is also an Advisory Committee (AC) as shown in section 2.3.5 of the Quality Manual. This committee was formed in response to the requirements of Paragraph 6.2 of ISO/IEC 17021. It was advised that the two committees may become merged into one.

## **5. CERTIFICATION OPERATIONS**

### **5.1. National Approval/Certification Methods**

All local certification work in this field is done under ATEX.

KEMA also issues certificates in a number of fields, including household, commercial and industrial products, assessment and certification of Quality Management Systems and Personnel Certification. It also issues KEMA mark, but this is not used for Ex products.

The KEMA Quality B.V. certification operations were reviewed in detail by the assessment team during the site assessment visit on 24, 25 and 26 March 2010. The site visit revealed compliance with ISO/IEC Guide 65 and IECEx requirements. The results of the last RvA audit, conducted in October 2009, were reviewed and found satisfactory.

### **5.2. Certification Policy**

The Certification Policy is embodied in its Quality policy which is included in the Quality Manual, section 1.1 and is appropriate for operation in the IECEx Equipment Certification Scheme.

### **5.3. Application for Certification**

The IECEx 02 overall procedures are laid down in KEMA's Quality Management System (QMS), see PROD-P-Ex04 (IECEx 02 product certification) and PROD-P-Ex05 (IECEx 02 site audits). The procedures are non-discriminatory.

### **5.4. Certification Decision**

The certification decision is taken by one of the two independent Ex Certification Managers (CM) appointed by KEMA Quality's Managing Director. The decision process is defined in PROD-P-Ex04. Only those managers who are authorized to turn a draft KEMA certificate into a current one have access to the appropriate IECEx password.

### **5.5. Suspension and Cancellation of Certificates**

Withdrawal, suspension and termination of certificates / certification agreements are covered by sections 16 and 19 of KEMA Quality's General Terms and Conditions. In addition, the IECEx 02 application forms that KEMA uses refer to IECEx 02 regarding suspension and withdrawal of certificates.

## **6. STATISTICS**

### **6.1. Certificates Issued**

Number of certificates issued under the IECEx, national or regional schemes in the preceding four years for each type of protection is shown below.



IECEx certificates:

Standards	Number of issued certificates				Total
	2006	2007	2008	2009	
IEC 60079-0 (Ed.4.0)	42	95	85	92	314
IEC 60079-0 (Ed.5)	0	0	6	32	38
IEC 60079-1 (Ed. 5)	10	19	4	10	43
IEC 60079-1 (Ed.6)	0	4	22	27	53
IEC 60079-7 (Ed.3)	13	29	7	22	71
IEC 60079-7 (Ed.4)	0	15	14	26	55
IEC 60079-11 (Ed.4)	22	27	25	12	86
IEC 60079-11 (Ed.5)	1	10	30	46	87
IEC 60079-15 (Ed.2)	0	16	14	4	34
IEC 60079-15 (Ed.3)	3	3	12	25	43
IEC 60079-18 (Ed.1)	0	0	0	3	3
IEC 60079-18 (Ed.2.0)	2	1	5	7	15
IEC 60079-26 (Ed.1)	9	25	24	23	81
IEC 60079-26 (Ed.2)	0	1	25	28	54
IEC 60079-27 (Ed.1.0)	5	10	16	6	37
IEC 60079-30-1 (Ed.1)	0	6	1	3	10
IEC 61241-0 (Ed.1)	11	26	35	56	128
IEC 61241-1 (Ed.1)	8	23	27	31	89
IEC 61241-11 (Ed.1)	6	6	22	35	69

KEMA has issued hundreds of ATEX certificates and site Notifications over the last 5 years as follows:

Year	No. of ATEX certificates	No. of ATEX Notifications
2005	246	74
2006	166	56
2007	151	64
2008	143	72
2009	154	76

Often IECEx CoCs are issued in combination with an ATEX (EC-) Type Examination Certificate.

## 7. DOCUMENTATION

### 7.1. Quality Manual

The on-line (accessible for all staff) KEMA Quality Manual (INFO-ALL-Q-1, dated 2008-07-10) covers all general requirements of ISO Guide 65 and ISO/IEC 17025. It is anticipated that the Manual will be updated as a result of the takeover of KEMA Quality B.V. by DEKRA.

### 7.2. Procedures

The KEMA Quality B.V. Quality on-line Management System (QMS) contains all procedures related to the activities of KEMA Quality B.V. This system is predominantly in English to assist with international use of the system. For IECEx 02, the specific procedures are PROD-P-Ex-04 and -05, covering product certification and site audits respectively. In addition there is a document General Manual EX Team that has been developed since the assessment visit. This describes in general terms the KEMA way



of working. It is intended as a guideline for all activities within Business Team Explosion Safety (Team Ex). Additional manuals are planned. All working documents like standard checklists, laboratory measurement forms, etc. are kept on EX Sharepoint.

### **7.3. Work Instructions**

There are no specific work instructions for the ExCB.

### **7.4. Records**

For each project a project file is made which includes all correspondence, assessment and test results and certificates. After completion of the work, the complete file is archived (product files in building H40, audit files related to the 3 year actual contract at the BSO in building H31). All records are appropriately stored.

### **7.5. Document Change Control**

All documents that are part of QMS are controlled according to KEMA Quality's procedures. The documents on EX Sharepoint are controlled using the procedure of the EX Team, using for each document an appointed document owner and document reviewer. Procedure FLOW-ALL-Q-M10 prescribes minimum retention times for documents. However, in practice obsolete documents are retained indefinitely in EX Sharepoint in a hidden directory not accessible for the users.

## **8. CONFIDENTIALITY**

The KEMA Quality BV management system ensures that all staff and any contractors (e.g. MTSA staff) sign a confidentiality agreement which also addresses "conflict of interest". Examples were cited of agreements signed by employees, contractor employees and members of committees. For more recent employees the confidentiality requirements are built into the employment contracts.

## **9. PUBLICATIONS**

KEMA Quality B.V. has published a number of papers relating to the Ex field including:

- a guidance paper on how to deal with the ATEX directive
- how to deal with Ex d cable glands (related to the flow chart in IEC 60079-14)
- several PCIC papers

## **10. NATIONAL ACCREDITATION**

KEMA Quality B.V. holds accreditation to ISO/IEC Guide 65 for various aspects of the certification business, including Ex. A copy of the certificate is included as Annex 3. However, KEMA does not hold an accreditation yet to ISO/IEC 17025 for the Ex laboratory activities. Its goal is to achieve ISO/IEC 17025 for all laboratory activities, including Ex, in 2010 or 2011.

## **11. RECOGNITION AND AGREEMENTS**

KEMA Quality B.V. agreements and recognitions include:

- Notified Body under ATEX
- IECEE CB Scheme
- IECEX 03 Scheme
- CSA

- FM
- USCG

## **12. INTERNAL AUDIT AND PERIODIC MANAGEMENT REVIEW**

KEMA Quality B.V. operates an internal audit program with results being raised at Management reviews.

For internal auditing KEMA Quality has instigated a system of 'topical' audits. The audit teams often include a cross-section of people including technical experts. Audits occur on a regular basis. The results of the last audit were reviewed and found to be satisfactory. There is a spreadsheet which documents the audit details, including its findings. At the time it was not clear how follow-up on the findings occur and it appeared that the auditors were not involved in this process. Subsequently KEMA put in place an improved follow-up system that satisfied the assessment team.

The records of the International Management Review meeting held in April 2009 were reviewed. Reference to IECEx was included in the schemes considered by the meeting and the meeting also covered all other necessary areas. The next meeting was scheduled for the end of April 2010.

## **13. SUBCONTRACTING, USE OF OTHER LABS AND USE OF OTHER LOCATIONS**

Most of the IECEx 02 work is done within KEMA Quality B.V. KEMA Quality B.V. uses MTSA Technopower B.V in Arnhem, NL, for Ex d measurements and preparation of test samples. One of the assessors together with a representative of KEMA Quality B.V. visited this operation during the assessment. There were some issues raised with at this operation but all were subsequently resolved to the satisfaction of the assessment team. Most of the issues had already been identified in an internal audit by KEMA and team felt this provided evidence of effective auditing by KEMA.

KEMA Quality B.V. also uses FM and CSA as subcontractors for ATEX audits. Occasionally, other KEMA laboratories are used to conduct specific tests, especially for FM and CSA testing (salt spray test, chemical compatibility tests). EXAM, Germany is used for testing in case of large samples that cannot be handled by KEMA.

There is a requirement regarding subcontracting in the Quality Manual. This addresses the need for accreditation to ISO/IEC 17025 or appropriate assessment.

## **14. TRAINING**

Training records are kept in the evidence and qualification files of the Ex staff. Individual or group training plans are developed where necessary, indicated by the Product Expert or by the staff member himself and approved by the Ex Operational Manager. Recently the new Japanese staff have received a 2 week basic Ex training. The Ex qualification list (expertise list) clearly shows (in a red color) Ex staff that is in training for certain standards or activities. Qualifications are reviewed by the Product Expert at least once a year.

A copy of the qualification list of KEMA personnel was provided. This includes a matrix that identifies staff competencies against key Ex aspects, including protection techniques. KEMA is moving to a company-wide system called PERSIS to include staff qualifications and competency but the Ex personnel were not in this system at the time of the assessment visit. This should ensure a more integrated system. In the mean time the assessment team felt that the matrix is sufficiently effective.

## **15. ASSESSMENT OF MANUFACTURERS AND ISSUE OF QARS**

KEMA Quality B.V. uses qualified auditors for the IECEx audits who conduct the audits and prepare the QAR. Planning of the audits is done by the EX Business Support Office (BSO); Qualified CMs review and approve the QARs. Sample files and QAR reports were reviewed with one of the auditors to determine the effectiveness of the process. These included NL/KEM/QAR06.0002/03, NL/KEM/QAR06.0005/06 and NL/KEM/QAR 07.0001/02. The reports were well prepared and together with other material on file provided evidence that the assessments are being carried out competently and appropriate QARs issued.

## **16. COMPLAINTS AND APPEALS (Including appeals to IECEx)**

Any disputes and complaints are dealt with according to article 17 of KEMA's General Terms and Conditions. In the IECEx 02 application forms that KEMA use for all IECEx projects; the client is made aware of the possibility to make an appeal to the IECEx ExMC.

## **17. SPECIAL FACTS TO BE NOTED**

### **17.1. Supporting Documentation**

Copies of additional supporting information for this assessment have been provided to the applicant and the IECEx Secretariat. These are included in a site assessment report and include:

- Details of issues raised and how these have been resolved
- Checklist for ISO/IEC Guide 65
- Assessor notes

## **18. COMMENTS (Including issues found during assessment)**

A number of issues were found during the assessment visit as shown earlier in this report. All were resolved to the satisfaction of the assessment team. Details of how they were resolved are included in Annex A of the site assessment report held by the Secretariat.

## **19. RECOMMENDATION**

Based on the assessment performed on 24, 25 and 26 March 2010, KEMA Quality B.V. is recommended for continued acceptance in the IECEx scheme as an IECEx Certification Body (ExCB) in the IECEx Equipment Certification Scheme according to the scope of the standards listed in this document, including the extension of scope.

Jim Munro  
Lead Assessor

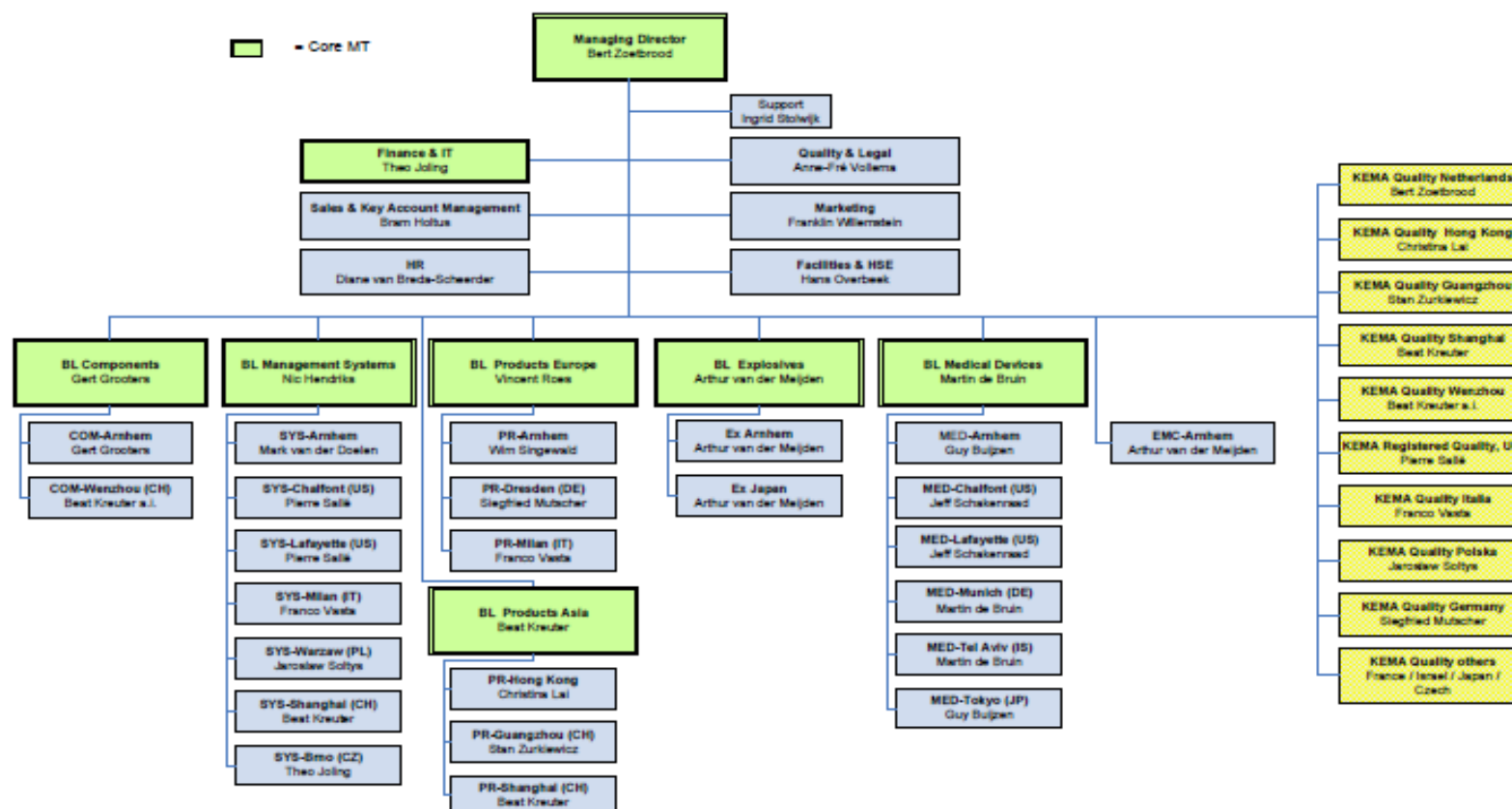
Vijay Varma  
Expert Assessor

Date: 16 September 2010

### **List of Annexes:**

1. Overall Organization Chart of KEMA Quality B.V.
2. Organization Chart of the Ex Business Line
3. Accreditation Certificate for Product and System Certification RvA C001, C001

# KEMA Quality Group



February 5, 2010

## Annex 2 Organization Chart of the Ex Business Line





**Annex 3  
Accreditation Certificates**

01-2017-2018-2019

**DUTCH ACCREDITATION COUNCIL RvA**

01-2017-2018-2019



The Dutch Accreditation Council RvA, by law appointed as  
the national accreditation body for The Netherlands,  
heroby declares that accreditation has been granted to:

**KEMA Quality B.V.  
Arnhem**

The organisation has demonstrated to be able to perform certification of products, in  
a competent, consistent and impartial manner.

This accreditation is based on an assessment against the requirements  
as laid down in NEN-EN 45011:1998, ISO/IEC Guide 65:1996.

The accreditation covers the activities as specified in the authorized  
annex bearing the registration number.

The accreditation is valid provided that the organisation  
continues to meet the requirements.

This accreditation with registration number:

**C 001**

is granted on 30 June 2010

This declaration is valid until

**1 May 2014**

The accreditation has been granted for the first time on

**26 September 1983**

The Chief Executive



In J.C. van der Poel



# DUTCH ACCREDITATION COUNCIL RvA

FD 800 2758 NL-3500 GT Utrecht



The Dutch Accreditation Council RvA, operating as accreditation body,  
hereby grants accreditation to:

## **KEMA Quality B.V. Arnhem**

The organisation has demonstrated to perform management system certification in a  
competent, consistent and impartial manner.

This accreditation is based on an assessment against the requirements specified in  
ISO/IEC 17021:2006 and in the RvA regulations.

The accreditation covers the certification schemes and working areas as specified in  
the authorized annex bearing the accreditation number.

The accreditation is valid provided that the organisation continues to meet the  
requirements.

This accreditation with number:

**C 013**

is granted on 16 December 2009 and is valid until

**1 May 2014**

The accreditation has been granted for the first time on

**7 April 1987**

for: ISO/IEC Guide 62 (C013)  
and

**28 August 2002**

for: ISO/IEC Guide 66 (C390)

The Chief Executive  
  
Ir. J.C. van der Poel