



Suspend and withdraw Procedure




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0 Normative Documents

- ISO/IEC 17065: Conformity assessment — Requirements for bodies certifying products, processes, and services
- ISO/IEC 17067: Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes
- ISO/IEC 17021-1: Conformity assessment — Requirements for bodies providing audit and certification of management systems
- ISO/IEC 17021-3: Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 3: Competence requirements for auditing and certification of quality management systems
- ISO/IEC 17026: Conformity assessment — Example of a certification scheme for tangible products
- ISO/IEC 17007: Conformity assessment — Guidance for drafting normative documents suitable for use for conformity assessment
- ISO 9000: Quality Management systems - Fundamentals and vocabulary
- ISO 9001: Auditing practices group guidance on third-party auditor impartiality and conflict of interest
- ISO/IEC 17000:2004: Conformity Assessment - Vocabulary and general principles
- ISO/IEC 17024:2012-11: Conformity assessment – Requirements for bodies operating certification of persons
- ISO 19011: Guidelines for auditing management systems
- IEC 31010: Risk management – Risk assessment techniques
- ISO 31000: Risk management — Principles and guidelines
- ISO/IEC 17030: Conformity assessment – General requirements for third-party marks of conformity
- ISO/IEC Guide 23: Method of indicating conformity with standards for third-party certification systems
- IECEx 02: Rules of Procedure
- IECEx OD 009: Operational Document - Procedures for the Issuing of IECEx Certificates of Conformity, IECEx Test Reports, and IECEx Quality Assessment Reports
- IECEx OD 035: A procedure to generate, discuss, report and publish ExTAG Decision Sheets
- IECEx OD 019: IECEx - Participation and System Fees
- IECEx OD 025: Guidelines on the Management of Assessment and Surveillance programs for the assessment of Applicant's Quality Systems, in accordance with the IECEx Scheme.
- IECEx OD 026: Guidelines for qualifying Lead Auditors and Auditors, in accordance with the IECEx System.
- IECEx OD 024: IECEx Rules of Procedure covering testing, or witnessing testing at a manufacturer's or user's facility
- IECEx OD 032: Guidelines and Information for IECEx Assessments

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Suspension & Withdrawal Procedure

- IECEx OD 060: IECEx Guide for Business Continuity – Management of Extraordinary Circumstances or Events Affecting IECEx Certification Schemes and Activities
- IECEx OD 209: Requirements and Guidelines for the Suspension, Cancellation, and Reinstatement of Certificates of Conformity
- IECEx OD 250: Guidance on the Management of IECEx Quality Assessment Reports (QARs)
- IECEx OD 011-1: Guidance on Use of the IECEx Internet based “On-Line” Certificate of Conformity System Part 1: General Information for IECEx On-line Certificate System (OCS) – Second Generation
- IECEx OD 011-2: Creating IECEx Equipment Certificates of Conformity CoCs and supporting Reports (ExTR Summary and QAR Summary)
- IECEx OD 010-2: Operational Document - Guidance for the development, compilation, issuing and receipt of ExTRs Part 2: Procedures and guidance
- IECEx OD 011-10: Guidance on Use of the IECEx Internet based "On-Line" Certificate of Conformity System, Part 10: IECEx On-Line Certificate System (OCS) - Second Generation - "Back Office" Operation
- IECEx OD 034: Operational Document - Guidance on the preparation of IECEx Equipment Certificates and Reports covering more than one identifiable item of equipment Ed. 3.0
- IECEx OD 033: IECEx Operations Manual – IECEx Unit Verification Certificates
- IECEx OD 203: Guidance on the definition of ‘manufacturer’ in relation to trade agents’ and ‘local assemblers’
- IECEx OD 017: Operational Document - Drawing and documentation Guidance for IEC Ex Certification – for use by Manufacturers and ExTLs
- IECEx OD 210: Guidance on the preparation of IECEx Equipment Certificates and Reports of a Modular Combination

1 Scope

This procedure applies to all activities of the CB and CBM-01.

Note 1: For the IECEx COCs, the IECEx OD 209 (Requirements and guidelines for the suspension, cancellation, and reinstatement of certificates of conformity) shall be followed.

Note 2: For the IECEx QARs, the IECEx OD 250 (Guidance on the Management of IECEx Quality Assessment Reports (QARs)) shall be followed.

2 Purpose: Procedure for suspension or withdrawal of certificates:

This procedure ensures a process for termination, reduction, suspension or withdrawal of registration certificates as the need arises. The following definitions apply:

- **Termination: Permanent ending or cancellation of a certificate**
- **Reduction: Decrease or limitation of the certificate’s validity or scope.**
- **Suspension: Temporary invalidation of a certificate of registration**
- **Withdrawal: Permanent invalidation of a certificate of registration**

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3 Mechanisms to Initiate Certificate of Conformity status change

3.1 General

Suspension of a certificate may occur for various reasons, as described in the product certification contract.

Regarding registration certification, a client organization enters suspension upon not engaging in the assessment as planned after three (3) months with justifiable reasons (e.g., financial hardship).

The three (3) months suspension is a decision EPIL carries through a committee. After three (3) months of suspension, it enters three (3) months of probation and withdrawal.

During suspension and then withdrawal, the organization refrains from using the certification instruments (certification of registration, seal-mark, report, and others associated with certification).

EPIL will seek ways to carry respectable organizations wishing to carry EPIL status for reasons such as temporary financial matters.

EPIL will suspend and proceed to withdraw organizations that are found. Not taking appropriate action may place in disrepute our brand and client organizations. To this effect, we carry a vision and signatory to a Charter to protect communities and consumers.

Suspensions and withdrawals are listed in the CBF-708-01, indicating the reason for the past client organization.

A client or EPIL can perform the status change of a certificate of conformity. The change in the status of a certificate may result in other certificates requiring the same action or impair other certified items' certification.

NOTE: There are many examples of certificates that will be affected by a certificate status change. Examples include, but are not limited to:

- "Trade agent" certificates of the certificate changing status.
- The suspension/withdrawal of a component certificate, resulting in equipment certificates that incorporate the Component requiring amendment.

Certificates of the certified item users may not be known to the client who is suspending/withdrawing the certificate.

3.2 Acting on Information Received

Attention is drawn to the possible confidential nature of material and information that may be provided to EPIL from a third party, e.g., copies of drawings, reports, and records.

EPIL acknowledges the receipt in such an instance and advises the third party that an investigation may be conducted. Any further communication is subject to confidentiality requirements.

3.3 Initiation by Client

A Client may initiate the suspension/withdrawal of a certificate. The client's initiation of the certificate suspension/withdrawal shall be by the person authorized by the client to do so.

The client shall provide:

- the certificate number/s of the certificate/s affected;

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- the reason for suspension/withdrawal;

The client should also provide details of any certificates they know that may be linked to or use the suspended/withdrawn certificate/s.

3.4 Initiation by EPIL

EPIL may initiate the Termination, reduction, suspension or withdrawal of a certificate if they determine that a reason provided in the following has been met.

- It is used misleadingly;
- The equipment no longer corresponds to the design of the certified equipment, or the QAR no longer adequately covers the relevant equipment;
- The manufacturer's quality system and associated quality plan no longer guarantee that equipment will be produced according to the certified equipment's design.
- It has been issued in error;
- The assessment by TL is deficient;
- The equipment design does not result in compliance with its referenced standards.
- Knowingly, infringement of the law; Evidence of non-compliance to regulatory/statutory requirements relevant to the certified product/management system or consumer protection;
- Objectively not carrying out activities that bear the signatory's legally binding commitment to protect consumers;
- The certified product/management system has persistently and seriously failed to meet contractual requirements;
- Failure to respond adequately to address NC(s) and the product scheme and technical documentation/management system no longer reflect the current organization and processes following EPIL policies and procedures;
- As a result of changes, acquisitions, and diversification of the organization without informing EPIL;
- A significant part of the product/management system is no longer validly implemented;
- Surveillance audits and recertification evaluation –audits not allowed to be conducted according to required frequency or as scheduled;
- The surveillance shows nonconformity with the requirements of such a nature that immediate withdrawal is not necessary;
- Violation of any of the specific product certification contract terms, a signed contract,
- Improper/inappropriate use of the certification mark and reference to certification;
- Consumers voluntarily request a temporary suspension through a recognized and generally accepted consumer advocate.
- Through objective and valid evidence, a client organization voluntarily requests the temporary suspension
- Evidence of infringement or request from a governmental authority that could affect the status of a certificate;
- Evidence of a non-effective action in the eventuality of serious/significant incidents.
- limited period of non-production

The certification manager of EPIL, the issuer of the decision-maker of certificate registration, decides on the action to be taken based on a review and duly consideration of the evidence. If the suspension is determined, the following process applies as follows:

Suspension of a certificate is generally initiated as the first step, followed by withdrawal if the concern is not

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resolved within due time. Dependent on the seriousness of the case, EPIL may decide on a direct withdrawal of the certificate.

When the appropriate action includes evaluation, review or a certification decision, the requirements in CBP-701-01 Certification Scheme system shall be fulfilled.

4 Actions to be completed before Termination, reduction, suspension or withdrawal

4.1 Actions to be completed before suspension/withdrawal

Before a certificate can be suspended/withdrawn, EPIL shall gather the following information:

- a) Details of the certificate(s) to be suspended
- b) Details of any other certificates that may be affected by the suspension that the client has provided

For suspensions/withdrawals initiated by the client, the details of the person requesting suspension, and confirmation that they have the authority to do so, are also required as the client's reason for the decision to suspend/cancel the certificate.

For suspensions/withdrawals initiated by EPIL, the reason for the suspension is also required. If the cause has been determined to be due to a non-conforming product, an investigation following clause "Informing of the market" must be initiated. Where the client is unaware of the preparation for certificate suspension/withdrawal, they shall be informed of the intended actions unless a covert investigation is ongoing before the suspension/withdrawal.

4.2 Actions to be completed before reduction

Before a certificate can be reduced, EPIL shall collect the following information: a) details of the certificate(s) to be reduced, and b) information about any other certificates that may be impacted by the reduction provided by the client. If a decision to reduce the scope of certification is made as a condition of reinstatement, the certification body shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure the reduced scope of certification is clearly communicated to the client and clearly specified in certification documentation and public information.

4.3 Actions to be completed before termination

If certification is terminated (by request of the client), the certification body shall take actions specified by the certification scheme and shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure it provides no indication that the product continues to be certified. If a scope of certification is reduced, the certification body shall take actions specified by the certification scheme and shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure the reduced scope of certification is clearly communicated to the client and clearly specified in certification documentation and public information.

4.4 Actions to be completed as part of a certificate of conformity suspension/withdrawal

The following activities are required to be completed as part of a certificate suspension/withdrawal:

- a) Certificate is suspended on the online system;

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- b) Client is informed of the change in certificate status and their obligations
- c) Other parties are informed following Clause "Informing of other parties."
- d) Products or services listed on suspended certificates may not be offered for sale, e.g.
- e) Investigation of non-conforming products

Where a certificate is to be suspended/withdrawn by EPIL due to a non-conforming product being placed on the market, it is principally the client's responsibility to investigate the potential effects of the non-conformance and communicate with EPIL.

The client shall conduct their investigation following ISO/IEC 80079-34 (for products intended to use in the explosive atmospheres), ISO 9001 (for other products) related clause for the control of the non-conforming product.

- f) Coordination with other parties in the case of safety issues

EPIL informs the regulatory authorities where a safety issue has been identified and announces the recipients of the affected products.

5 Investigation of non-conforming products

5.1. General

Where a certificate is to be suspended/withdrawn by EPIL due to a non-conforming product being placed on the market, it is principally the client's responsibility to investigate the potential effects of the non-conformance and communicate with EPIL.

The client shall conduct their investigation following the following ISO/IEC 80079-34 (for products intended to use in the explosive atmospheres), ISO 9001 (for other products) related clause for controlling the non-conforming product.

5.2. Coordination with other parties in the case of safety issues

EPIL informs the regulatory authorities if a safety issue has been identified and informs the affected products' recipients.

5.3. Informing other parties

5.3.1 General

The change in the status of a certificate may impact other parties; thus, EPIL identifies which parties require informing and informing those parties.

The parties that may require informing are, but are not limited to:

- Client
- Public (through the online certificate of conformity system)
- Regulatory authorities
- Other interested parties

NOTE: The Client's responsibility is to identify and inform the certified product recipients under suspension/withdrawal.

Other interested parties may include certification bodies using the EPIL certificate and EPIL TR for local/regional certification.

The security features of the EPIL "Online" Certificate System require that changing the status of a product Online Certificate from "Current" to "Suspended" or "Withdrawn" can only be completed by the project manager. The following information is required for the project manager to complete this action:

- Certificate/s of Conformity affected
- Reason for suspension/withdrawal, including proposed details to be placed on the suspended/withdrawn certificate
- Instructions for recipients of the affected product, if required
- For suspensions, the expected outcome (reinstatement after the completion of specific actions or withdrawal)
- What is the impact on products supplied to the market before the date of suspension/withdrawal?
- The effective date of status change

5.3.2 Client

When the status of a certificate is changed, EPIL will inform the client of the status change. EPIL provides instruction to the client on what they are obliged to do.

6 Suspension or withdrawal not as a result of a non-conforming product

The client's communication regarding the suspension/withdrawal of a certificate/s in form CBF-711-01 makes them aware that they are no longer permitted to describe the products covered by the certificates as "EPIL certified," nor shall they affix the EPIL Conformity Mark to the product. They also are made aware that, with immediate effect, they are required to update any publicly available information (such as website and marketing material) to remove any association between EPIL and the products in the affected certificates.

EPIL informs the client in writing (form CBF-711-01) that they are required to notify any trade agents/distributors/representatives involved in the sales and distribution of the affected product/s that the certificates are suspended/withdrawn and that they are required to instruct them to remove any association between EPIL and the products in the affected certificates.

Note: The communication shall include:

- (a) A statement on the decision to suspend the certificate, including a proper description of the situation, argumentation, and reference to objective evidence
- (b) The right to respond and appeal the decision

A 15 working days' notice for response and appeal is given. An appeal may be lodged through the complaint's procedure.

- (c) Start date of the suspension (generally from the receipt of the communication)
- (d) Conditions and due date of required action to revoke the suspension and the consequence if satisfactory actions are not performed
- (e) The means of follow-up by EPIL to verify that conditions have been met and effective corrective actions have occurred
- (f) A statement that the certificate is invalid during suspension and that use of advertising matter containing a reference to certification is not permitted during the suspension
- (g) A statement that both the certification of registration bearer and EPIL inform inquiries that the certificate is suspended

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(h) A certificate shall not be suspended for more than six months.

6.1 Suspension or withdrawal as a result of a non-conforming product

The client's communication regarding the suspension/withdrawal of a certificate(s) of a non-conforming product includes the information as detailed in Clause 6.2.1. Still, it is to be supplemented with the following additional information.

The client will be informed that the certificate suspension will remain until the agreed-upon remedial actions have been completed and EPIL is satisfied that no other non-conforming product will be placed on the market.

They will also be informed that if the remedial action is not completed satisfactorily, they cannot demonstrate that no further non-conforming product will be placed on the market. The certificates will be withdrawn following the relevant parts of Clause 5, and further action will be taken to rectify the issue of non-conforming products in the field.

6.2 Follow up

EPIL verifies that the conditions communicated are met and that the corrective actions are effective. Depending on this verification EPIL will either:

- (a) Declare a positive result, revoke the suspension and declare a valid certificate,
- (b) Set a negative result due to failure to resolve the issues that resulted in suspension; this situation will likely result in permanent withdrawal of registration certification. (Read on) in either case, the client will receive a communication confirming the result.

After suspending a certificate, the decision to reinstate it is communicated to the bearer of the registration certification by formal communication (CBF-711-01).

6.3 Reinstatement following suspension

The communication to the Client in CBF-711-01 regarding the reinstatement of a certificate/s makes them aware that they are again permitted to describe the products covered by the certificates as "EPIL Certified" reattach the EPIL Conformity Mark to the product. They may also reinstate any publicly available information that refers to the affected certificates' products as certified.

6.4 Withdrawal following Suspension

Communicating with the Client in CBF-711-01 regarding the withdrawal of a certificate(s) makes them aware that their certification is now withdrawn and that reinstatement is no longer possible.

6.5 Public (through the online certificate of conformity system)

EPIL On-Line Certificate System explains the reason for the certificate suspension/withdrawal and, if appropriate, instructions for recipients of the products covered by the affected certificate.

6.6 Regulatory Authorities, e.g., Market surveillance authorities

Suppose a certificate of registration is being suspended/withdrawn due to non-conforming, where a potentially non-conforming product has been placed on the market. In that case, EPIL complies with its national regulatory requirements, including notification to authorities, e.g., Market Surveillance Authorities.

When contacting the relevant regulatory authorities, EPIL provides the following information:

- Overview of the product/s affected, including:
- An estimate of quantities affected;
- An explanation of the industries it may be being used in;
- The likelihood of an incident occurring
- The likely (primary) incident that could occur
- Reason for suspension/withdrawal
- Certificate/s of Conformity affected
- For suspensions, the expected outcome (reinstatement after the completion of specific actions or withdrawal)

6.7 Complainant

Where a suspension/withdrawal has occurred, following information provided by a complainant, EPIL follows its own complaints procedures CBP-713-01.

6.8 Recipients of a certified product under suspension/withdrawal

Suppose a certificate of conformity is suspended or withdrawn due to a non-conforming or potentially non-conforming product being placed on the market. In that case, the recipients of those certified products will need to be notified.

The client's responsibility is to inform the market of any issues that may affect users. The client shall determine whom the recipients of the potentially affected products are and provide them with the following:

Overview of the product/s affected, including

- Model numbers
- Certificate number
- The likelihood of an incident occurring
- The likely (primary) incident that could occur
- Instructions on what they are to do to mitigate the risk;

NOTE: Examples include: withdrawal of a product from service; replacement of a part of the product; amendment of the operating parameters; increase in service intervals; completion of an inspection process.

7 Informing the market

7.1 General

Throughout the process of suspending or withdrawing certification, the confidentiality of the client will require retention. However, due to the suspension or withdrawal of certificates, certain information will need to be released to the public by EPIL on its website: www.epil.ir. In determining the level of information to be released, the following should be considered:

- a) Is there an impact on products already supplied before the date of suspension/withdrawal;
- b) Are products supplied before the date of suspension/withdrawal currently under review by EPIL and/or manufacturer, and are further actions, such as withdrawal or rectification, a possible outcome of that review;
- c) Have products supplied before the date of suspension/withdrawal been determined to require withdrawal from the market or rectification to bring them into compliance;

7.2 No impact on products already supplied

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The supplied products are compliant and unaffected by the certificate suspension/withdrawal. No further information required in Clause 6 is necessary to be released to the public.

7.3 Impact on products already supplied

If the products already supplied before the date of suspension/withdrawal and have been determined as non-conforming, EPIL ensures that advice is provided on products already in the market before the date of suspension or withdrawal, including:

- a) Remedial action as required, such as product recalls, public notices, etc
- b) Notification to Regulatory and/or Market Surveillance Authorities as required
- c) Notification to other interested parties as necessary.

This information will be provided within 30 days of suspension/withdrawal of the certificate/s of conformity.

8 Withdrawal or reinstatement of a certificate of conformity following suspension

8.1 General

A certificate cannot remain suspended indefinitely, and the certification manager will review the certificate's status at regular intervals.

Where EPIL initiated the suspension, the maximum duration of certificate suspension should not exceed six months.

EPIL decides when to change the status of a certificate from 'Suspended' to either 'Withdrawn' or 'Current.'

NOTE: Regular intervals are considered to be periods of 3 months.

8.2 Reinstatement of a certificate of conformity to Current following suspension

The status of a certificate of conformity may be changed from 'Suspended' to 'Current' for one of the following reasons:

- The client requested the certificate suspension and has requested that the certificate status be changed to 'Current,' as the product will return to production.
- EPIL has contacted the client after an agreed length of time after suspension, and the client has confirmed that the product will return to production.
- Pre-agreed conditions regarding the suspension of the certificate have been met within the agreed timeframe.

8.3 Withdrawal of a certificate of conformity following suspension

The status of a certificate of conformity may be changed from 'Suspended' to 'Withdrawn' for one of the following reasons:

- (a) The client has requested that the certificate status be changed to 'Withdrawn'; the product will no longer be produced.
- (b) EPIL has contacted the client after an agreed length of time after suspension, and the client has confirmed that the product will no longer be produced or has not responded.
- (c) Pre-agreed conditions regarding the suspension of the certificate have not been met within the agreed

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timeframe.

- (d) The client does not meet the conditions of suspension
- (e) The surveillance shows that the nonconformity is serious;
- (f) The client does not wish to prolong the contract;
- (g) The standard or rules are changed, and the client either will not or cannot ensure conformity with the new requirements
- (h) The client fails to comply with the due settlement of financial obligations
- (i) The product is no longer made, or the client goes out of business
- (j) On the grounds of other provisions certified in the product certification contract
- (k) A suspension is not considered to be an adequate action.

The decision to withdraw a certificate shall be formally communicated to the client, including the requirements to:

- (1) Terminate use of the certification mark and any reference to certification, and
- (2) Return to EPIL or evidence of mutilation of the certification of registration and copies.

With the certification of registration bearer, the client has a right to appeal; an appeal may be lodged through the complaint's procedure.

Depending on the reason for the withdrawal, the following schedule of notice will be followed:

A situation requiring the dispatch of notice that can lead to withdrawal	Days of notice before withdrawal
Manufacturer's wish to withdraw	30 days
EPIL determines that the product is hazardous	None
Violation of an existing standard for reasons other than safety	max. 60 days
Non-payment of charges to EPIL	max. 30 days
Failure to meet other provisions of the licensing agreement	max. 60 days
Mandatory conformity with new requirements about the revision of a standard	As determined by the product certification scheme

Suspension, withdrawal, termination, or reinstating after the suspension of a client will be published on the site of EPIL.

Annex 1: Example text for notification of Applicant of certificate suspension/cancellation

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**1- Text to be used where certificate suspension is not due to a non-conforming product**

Further to ***, we can confirm that these certificates have now been suspended until further notice/canceled.

[INSERT LIST OF CERTIFICATES HERE]

Please be aware that you are no longer permitted to describe the products covered by these certificates as “EPIL certified”, nor shall you affix the EPIL Conformity Mark to the product. Please also ensure that you immediately update the following to remove any association between EPIL and the products in the affected certificates:

- a) Website
- b) Marketing material (data sheets, sales brochures, sales catalogs), as necessary
- c) Product labeling
- d) Packaging

However, products produced prior to the date of suspension/cancellation may be described as being certified.

*** Replace with the appropriate text describing the reason for suspension/cancellation. The following examples may be used:

Your recent request to suspend/cancel the certificate/s of conformity listed below

Recent information we have received regarding the certificate/s of conformity listed below,

The recent correspondence of our intentions to suspend/cancel the certificate(s) of conformity listed below

2- Text to be used where certificate suspension is due to a non-conforming product

The following text is supplementary to the text in 1:

The certificate suspension will remain in effect until the agreed-upon remedial actions have been completed and that we are satisfied that no further non-conforming product will be placed on the market.

Should the remedial actions not be satisfactorily completed in the agreed time or you are unable to demonstrate that no further non-conforming product will be placed on the market, the certificate(s) will be canceled and further action to rectify the issue of non-conforming products in the field may be taken.

Annex 2: Example text for notification of Applicant of certificate reinstatement or cancellation**1- Reinstatement of the certificate(s)**

We can confirm that the following certificates previously suspended have now been reinstated:

[INSERT LIST OF CERTIFICATES HERE]



You are now permitted to again describe the products covered by these certificates as “EPIL certified” and where applicable, you may reattach the EPIL Conformity Mark to the product. You may now update the following to reintroduce any association between EPIL and the products in the affected certificates:

- a) Website
- b) Marketing material (data sheets, sales brochures, sales catalogues)
- c) Product labelling
- d) Packaging

2- Cancellation of certification

We can confirm that the following certificates previously suspended have now been cancelled:

[INSERT LIST OF CERTIFICATES HERE]

The cancellation of EPIL certificates of conformity means that reinstatement is no longer possible.