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 | **ExMC/1259/CD****July 2017**  |

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

**To: Members of the IECEx ExMC**

**Title: Draft new Operational Document - Requirements when dealing with the Suspension or Cancellation of IECEx Certificates of Conformity issued under the IECEx 02 Certified Equipment Scheme**

**INTRODUCTION**

During the 2016 meeting of WG1 a special AdHoc Group was formed to prepare minimum requirements and guidelines for dealing with matters arising from the suspension or cancellation of IECEx Certificates of Conformity issued under the IECEx 02 Certified equipment Scheme. A verbal report was given during the 2016 ExMC Umhlanga meeting.

Further work was undertaken by both ExMCWG1 and the AdHoc Group during May and June 2017 with the AdHoc Group holding a special meeting in Geneva in June 2017, to finalise this proposed Draft Operational Document.

This Draft Operational Document is therefore submitted for ExMC Consideration during the 2017 Washington meeting.

**IECEx Secretariat**

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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IECEx operational document

IECEx Certified Equipment Scheme

IECEx OD 0xx Edition 1.0

Guidelines for the Suspension, Cancellation and Reinstatement of Certificates of Conformity

INTRODUCTION

This Operational Document, OD xxx, is supplementary to the operational manuals and procedures of the IECEx Certified Equipment Scheme, operated by IECEx Certification Bodies (ExCBs). The document provides clarification to IECEx Certification Bodies (ExCBs) within the IECEx Certified Equipment Scheme on the steps to be taken and processes to be followed when suspending or cancelling an IECEx Certificate of Conformity.

The document has been produced as there was limited guidance available to certification bodies on the appropriate steps that should be taken when suspending or cancelling an IECEx Certificate of Conformity, resulting in potential inconsistences in the approach taken.  Although all certification bodies have their own procedures in dealing with suspensions and cancellations, in order to ensure that the certification bodies of the IECEx Certified Equipment Scheme operate in a fair and consistent manner, the IECEx provides suitable guidance to all its ExCBs through this document.

Document History

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| --- | --- |
| Date | Summary |
| 2017 XX | Edition 1.0 |

IECEx operational document

IECEx Certified Equipment Scheme

IECEx OD 0xx Edition 1.0

Requirements for the Suspension, Cancellation and Reinstatement of Certificates of Conformity

# Scope

This Operational Document, OD xxx, specifies the requirements and provides guidance for suspension, cancellation and reinstatement of certificates.

The document is applicable to certificates of conformity under the IECEx Certified Equipment Scheme.

IECEx ExCBs within the IECEx Certified Equipment Scheme are also recognised certification bodies within their own region. As a result, they are required to fulfil their local, legal obligations. Therefore this document should be treated as a supplement to those requirements.

# Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 80079-34, Explosive atmospheres – Part 34: Application of quality systems for equipment manufacture

IECEx 02, IEC System for Certification to Standards relating to Equipment for use In Explosive Atmospheres (IECEx System) – Rules of Procedure

OD 011-1, IEC System for Certification to Standards relating to Equipment for use In Explosive Atmospheres (IECEx System) – Guidance on Use of the IECEx Internet based “On-Line” Certificate of Conformity System – Part 1: General Information

OD 011-2, IEC System for Certification to Standards relating to Equipment for use In Explosive Atmospheres (IECEx System) – Guidance on Use of the IECEx Internet based “On-Line” Certificate of Conformity System – Part 2: Creating IECEx Equipment Certificates of Conformity CoCs

# Terms and definitions

For the purposes of this document, the following terms and definitions apply.

Applicant initiated certificate suspension

A request, made by the applicant to the certificate issuing ExCB, to change the status of a "current" certificate to "suspended".

EXAMPLE Typical example would be a product that the manufacturer has temporarily taken out of production, or has ceased to produce but may resume production of in the near future.

Applicant initiated certificate cancellation

A request, made by the applicant to the certificate issuing ExCB, to change the status of a "current" certificate to "cancelled".

EXAMPLE Typical example would be a product that the manufacturer has permanently taken out of production and does not intend to resume production of in the future.

Note 1 to entry: Certificate cancellations are permanent, a certificate cannot be reinstated after cancellation.

Applicant initiated certificate cancellation after suspension

A request, made by the applicant to the certificate issuing ExCB, to change the status of a "suspended" certificate to "cancelled".

EXAMPLE Typical example would be a product that the manufacturer had temporarily taken out of production, or had ceased to be produced but production of which has now been determined as being permanently taken out of production.

Note 1 to entry: Certificate cancellations are permanent, a certificate cannot be reinstated after cancellation.

Applicant initiated certificate reinstatement after suspension

A request, made by the applicant to the certificate issuing ExCB, to change the status of a "suspended" certificate to "current".

EXAMPLE Typical example would be a product that the manufacturer had temporarily taken out of production, or had ceased to be produced but production of which is now to resume, with or without modification.

Certification Body initiated certificate suspension

An action completed by the Certification Body responsible for the issuing of the certificate, made to change the status of a "current" certificate to "suspended".

EXAMPLE Typical reasons for suspension are provided in IECEx 02 (Ed. 5.1) clause 9.11.

Certification Body initiated certificate cancellation

An action completed by the Certification Body responsible for the issuing of the certificate, made to change the status of a "current" certificate to "cancelled".

EXAMPLE Typical reasons for cancellation are provided in IECEx 02 (Ed. 5.1) clause 9.11.

Note 1 to entry: Certificate cancellations are permanent, a certificate cannot be reinstated after cancellation.

Certification Body initiated certificate cancellation after suspension

An action completed by the Certification Body responsible for the issuing of the certificate, made to change the status of a "suspended" certificate to "cancelled".

EXAMPLE The applicant of a suspended certificate has failed to meet pre-arranged corrective actions imposed upon them as a result of a certificate misuse within a given timeframe.

Note 1 to entry: Certificate cancellations are permanent, a certificate cannot be reinstated after cancellation.

Certification Body initiated certificate reinstatement after suspension

An action completed by the Certification Body responsible for the issuing of the certificate, made to change the status of a "suspended" certificate to "current".

EXAMPLE The applicant of a suspended certificate has successfully completed pre-arranged corrective actions imposed upon them as a result of a certificate misuse, and within a given timeframe.

Market Surveillance Authority

**Regulatory Authority**

An organisation, often a public authority, whose responsibility is to monitor the safety and conformity of products against the local or regional law.

# Mechanisms to initiate Certificate of Conformity status change

## General

The initiation of the change in status of a certificate of conformity can be performed either by the applicant or the certification body. The change in status of a certificate may result in other certificates requiring the same action, or may impair the certification of other certified items.

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

* “Trade agent” certificates of the certificate changing status.
* The suspension/cancellation of an Ex Component certificate, resulting in equipment certificates which incorporate the Ex Component requiring amendment.
* Certificates of users of the certified item, these may not be known to the applicant who is suspending/cancelling the certificate.

Reasons for the suspension/cancellation of a certificate are provided in IECEx 02 clause 9.11.

## Acting on Information Received

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

In such an instance, the ExCB receiving the information may acknowledge the receipt and advise the third party that an investigation may be conducted. Any further communication is subject to confidentiality requirements.

### Initiation by applicant

An applicant may initiate the suspension/cancellation of a certificate. The initiation of the certificate suspension/cancellation by the applicant shall be by the person authorised by the applicant to do so.

The applicant is to provide: the certificate number/s of the certificate/s affected; the reason for suspension/cancellation; the applicant should provide details of any certificates they are aware of that may be linked to, or make use of, the suspended/cancelled certificate/s.

### Initiation by certification body

A certification body may initiate the suspension/cancellation of a certificate should they determine that a reason provided in IECEx 02 clause 9.11 has been met.

NOTE: IECEx 02 edition 5.1 provides the following reasons for certificate cancellation initiated by the certification body:

* It is used in a misleading way;
* The Ex equipment no longer corresponds to the design of the certified equipment, or the QAR no longer adequately covers the relevant Ex equipment;
* The manufacturer's quality system and associated quality plan no longer provides adequate confidence that Ex equipment will be produced in conformity with the design of the certified equipment.
* It has been issued in error;
* The assessment by an ExTL has been found to be deficient;
* The equipment design cannot be considered as explosion protected.

# Actions to be completed prior to suspension/cancellation

Before a certificate can be suspended/cancelled the following information shall be gathered by the certification body:

1. Details of the certificate/s to be suspended
2. Details of any other certificates that may be affected by the suspension that have been provided by the applicant

For suspensions/cancellations initiated by the applicant, the details of the person making the request for suspension, and confirmation that they have the authority to do so, is also required, as well as the reason provided by the applicant for the decision to suspend/cancel the certificate.

For suspensions/cancellations initiated by the certification body, the reason for suspension is also required. If the reason has been determined to be due to non-conforming product in the market, an investigation in accordance with clause 9 is required to be initiated. Where the applicant is unaware of the preparation for certificate suspension/cancellation, they shall be informed of the intended actions unless a covert investigation is ongoing prior to the suspension/cancellation.

# Actions to be completed as part of a certificate of conformity suspension/cancellation

The following actions are required to be completed as part of a certificate suspension/cancellation:

1. Certificate is suspended on the on-line system following the procedures in operational document OD 011-1 and OD 011-2;
2. If the associated QAR includes more than the suspended certificate/s of conformity, QAR is to be amended to remove suspended certificates;
3. Applicant is informed of the change in certificate status and their obligations (see Annex B for example text that may be used)
4. Other parties are informed in accordance with Clause 8.
5. Products or services listed on suspended certificates may not be offered for sale, e.g., refer to IECEx 02.
6. Investigation of non-conforming products
7. General

Where a certificate is to be suspended/cancelled by a certification body due to non-conforming product being placed on the market, it is principally the responsibility of the applicant to investigate the potential effects of the non-conformance and to communicate with the certification body/bodies responsible for the certificate of conformity and QAR.

The applicant shall conduct their investigation in accordance with ISO/IEC 80079-34 Clause 8.3 for the control of non-conforming product.

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

Where a safety issue has been identified, in addition to informing the recipients of the affected products, the Certification Body shall inform the IECEx secretariat in accordance with Clause 8.2 and regulatory authorities shall be informed in accordance with Clause 8.4.

# Investigation of non-conforming products

## General

Where a certificate is to be suspended/cancelled by a certification body due to non-conforming product being placed on the market, it is principally the responsibility of the applicant to investigate the potential effects of the non-conformance and to communicate with the certification body/bodies responsible for the certificate of conformity and QAR.

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# Informing of other parties

## General

The change in the status of a certificate may have an impact on other parties, thus, the certification body shall identify which parties require informing and shall inform those parties.

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

* IECEx Secretariat
* Applicant
* Public (through the on-line certificate of conformity system)
* Regulatory authorities
* Other interested parties

NOTE: It is the applicant’s responsibility to identify and inform the recipients of certified product under suspension/cancellation.

Other interested parties may include certification bodies using the IECEx certificate and ExTR towards local/regional certification.

## IECEx Secretariat

The security features of the IECEx “On-Line” Certificate System require that changing the status of an IECEx On-line Certificate from “Current” to “Suspended” or “Cancelled” can only be completed by the IECEx secretariat acting as the System’s Administrator, upon instruction from the ExCB that issued the IECEx Certificate, that the ExCB has taken such a decision therefore any certificate suspension is required to be communicated to the IECEx secretariat. The following information is required for the secretariat to complete this action:

* Certificate/s of Conformity affected
* QAR/s affected
* Reason for suspension/cancellation, including proposed details to be placed on the suspended/cancelled certificate (see 8.4)
* Instructions for recipients of the affected product, if required (see 8.4)
* For suspensions, the expected outcome (reinstatement after the completion of certain actions or cancellation)
* What is the impact to Ex products supplied to the market prior to the date of suspension/cancellation
* Effective date of status change

## Applicant

When the status of a certificate is changed, the certification body is required to inform the applicant of the change in status. The certification body shall provide instruction to the applicant on what they are obliged to do.

### Suspension or Cancellation not as a result of non-conforming product

The communication to the applicant with regards to the suspension/cancellation of a certificate/s should make them aware that they are no longer permitted to describe the products covered by the certificates as “IECEx certified”, nor shall they affix the IECEx Conformity Mark to the product. They should also be 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 IECEx and the products in the affected certificates.

The certification body should inform the applicant that they are required to inform any trade agents/distributors/representatives involved in the sales and distribution of the affected product/s that the certificates are suspended/cancelled and that they are required to instruct them to remove any association between IECEx and the products in the affected certificates. An example of text to address this requirement is provided in B.1.

### Suspension or Cancellation as a result of non-conforming product

The communication to the applicant with regards to the suspension/cancellation of a certificate/s of a non-conforming product should include the information as detailed in Clause 8.3.1 but is to be supplemented with the following additional information.

The applicant shall be informed that the certificate suspension will remain in effect until the agreed upon remedial actions have been completed and the certification body is satisfied that no further non-conforming product will be placed on the market.

They should also be informed that if the remedial action is not completed satisfactorily and they are unable to demonstrate that no further non-conforming product will be placed on the market, then the certificates will be cancelled in accordance with the relevant parts of Clause 7 and further action will be taken to rectify the issue of non-conforming products in the field.

An example of the additional text to address this requirement is provided in B.2.

### Reinstatement following suspension

The communication to the applicant with regards to the reinstatement of a certificate/s should make them aware that they are again permitted to describe the products covered by the certificates as “IECEx certified”, and reaffix the IECEx Conformity Mark to the product. They may also reinstate any publicly available information that refers to the products in the affected certificates as being IECEx certified.

### Cancellation following suspension

The communication to the applicant with regards to the cancellation of a certificate/s should make them aware that their certificate is now cancelled and that reinstatement is no longer possible.

## Public (through the on-line certificate of conformity system)

Through the on-line certificate, the reason for the certificate suspension/cancellation along with, if appropriate, instructions for recipients of the products covered by the effected certificate.

This action is to be completed by the IECEx Secretariat but requires the input of the ExCB.

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

If a certificate of conformity is being suspended or cancelled due to non-conforming, where there is potentially non-conforming product having being placed on the market, the ExCB will be required to comply with their national regulatory requirements, including notification to authorities, e.g. Market Surveillance Authorities.

When contacting the relevant regulatory authorities the ExCB may need to provide 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/cancellation
* Certificate/s of Conformity affected
* For suspensions, the expected outcome (reinstatement after the completion of certain actions or cancellation)

NOTE: This will provide the market surveillance authority some indication of the severity of the non-conforming product. The principle role of market surveillance authorities is protection public safety, a non-conforming product may be determined as remaining safe or with a low risk of incident or a higher risk of incident. The market surveillance authorities will most likely need to work with the certification body to determine what the level of risk is and whether they need to act quickly or not.

## Complainant

Where a suspension/cancellation has occurred following information provided by a complainant, the Certification Body should follow their own complaints procedure.

## Recipients of certified product under suspension/cancellation

If a certificate of conformity is to be suspended or cancelled due to non-conforming, or potentially non-conforming product being placed on the market, the recipients of those certified products may need to be notified.

Principally, it is the responsibility of the applicant to inform the market of any issues that may affect users. The applicant shall determine who 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 product from service; replacement of a part of the product; amendment of the operating parameters; increase in service intervals; completion of an inspection process.

# Informing of the market

## General

Throughout the process of suspending or cancelling certification, the confidentiality of the client will require retention. However, due to the nature of suspension or cancellation of certificates, certain information will need to be released to the public. In determining the level of information to be released the following should be considered:

1. Is there an impact on products already supplied prior to date of suspension/cancellation (see clause 10.2);
2. Are products supplied prior to the date of suspension/cancellation currently under review by the ExCB and/or manufacturer and are further actions, such as withdrawal or rectification a possible outcome of that review (see clause 10.3);
3. Have products supplied prior to the date of suspension/cancellation been determined to require withdrawal from the market or rectification to bring them into compliance (see clause 10.4);

## No impact on products already supplied

Where the products already supplied are compliant and are unaffected by the certificate suspension/cancellation, no further information to that required in clause 8 is necessary to be released to the public.

## Impact on products already supplied

Where the products already supplied prior to the date of suspension/cancellation have been determined as non-conforming, the ExCB shall ensure that advice is provided on Ex products already in the market prior to the date of suspension or cancellation, including:

1. Remedial action as required, such as product recalls, public notices, etc
2. Notification to Regulatory and/or Market Surveillance Authorities as required
3. Notification to other interested parties as necessary.

This information shall be provided within 30 days of suspension/cancellation of the certificate/s of conformity.

# Cancellation or reinstatement of a certificate of conformity following suspension

## General

A certificate cannot remain suspended indefinitely. The status of the certificate shall be reviewed by the ExCB at regular intervals.

Where the suspension was initiated by the ExCB, the maximum duration of certificate suspension should not exceed 12 months.

The certification body shall decide when to change the status of a certificate from suspended to either ‘cancelled’ or ‘current’.

NOTE: Regular intervals are considered to be time periods of between 3 and 6 months.

## 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 applicant had requested the certificate suspension and has subsequently requested that the certificate status be changed to ‘current’, as the product will return to production.
* The applicant has been contacted by the certification body after an agreed length of time after suspension and the applicant 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.

## Cancellation of a certificate of conformity following suspension

The status of a certificate of conformity may be changed from ‘suspended’ to ‘cancelled’ for one of the following reasons:

* The applicant has requested that the certificate status be changed to ‘cancelled’, the product will no longer be produced.
* The applicant has been contacted by the certification body after an agreed length of time after suspension and the applicant has confirmed that that the product will no longer be produced, or has not responded.
* Pre-agreed conditions regarding the suspension of the certificate have not been met within the agreed timeframe.

# Ongoing reporting of status

## Applicant requirements

### Certificates not under investigation

Applicants who have requested the suspension of their certificate should keep the certification body informed of the status of the product at regular, pre-arranged intervals. A certificate cannot remain suspended indefinitely, therefore, should the manufacturer determine that a recommencement of production of a certified product is unlikely, they should inform the certification body to cancel the certificate.

### Certificates under investigation

Applicants of certificates under investigation into a non-conformance shall update the certification body of its progress. The certification body and applicant should agree to the frequency, minimum content and lines of communication of the updates.

If the applicant does not provide the agreed update in time, the certificate should be cancelled.

If, during the course of the investigation, the applicant ceases trading and is no longer in a position to continue, the certification body shall seek the assistance of the IECEx Secretariat and regulatory and/or market surveillance authorities.

NOTE: A possible outcome of such a situation occurring is the mandatory extraction of the product in the field, enforced by the regulatory and/or market surveillance authorities.

## Certification Body requirements

### Certificates not under investigation

The certification body should keep the IECEx Secretariat informed of any updates relating to a suspended certificate.

### Certificates under investigation

Certification bodies of certificates under investigation into a non-conformance shall update the IECEx Secretariat, and any other involved organisation, of its progress. The certification body, IECEx Secretariat, and any other involved organisation should agree to the frequency, minimum content and lines of communication of the updates.

If the applicant does not provide the agreed update in time, the incident may be reported to the IECEx ExMC to determine if further action or intervention is required.

1. (informative)

Checklist for actions to be completed by the ExCB throughout suspension process
	1. Checklist

|  |  |
| --- | --- |
| Task to be completed |   |
| **Actions to be completed before suspension (Clause 5)** |
| The person making the request has the authority to do so |   |
| Identify certificate/s to be suspended |   |
| Request list of any linked certificates from the applicant (clause 4.3.1 and clause 5, a)) |   |
| **Actions to be completed as part of the suspension (Clause 6)** |
| If all Certificates of Conformity on a  QAR are suspended, the QAR shall also be suspended |   |
| If the associated QAR includes more than the suspended certificate/s of conformity, QAR is to be amended to remove suspended certificates |   |
| Complete a search for any other certificates that may be affected by the suspension |   |
| Check on the Manufacturers marketing material, e.g. website in case they are still advertising that their products are covered by valid IECEx Certificates |   |
| **Actions to be completed in the event of non-conforming product in the market (Clause 9.3)** |
| Advice to the market concerning Ex products already in the market prior to the date of suspension or cancellation |   |
| Regulatory/market surveillance authorities informed if necessary |   |
| **Actions to complete prior to reinstatement (Clause 10.2)** |
| QAR includes the reinstated certificate |   |
| Applicant is informed of reinstatement |   |
| IECEx secretariat is informed of reinstatement |   |
| Any issues arisen as a result of the suspension have been addressed (non-conformities have been addressed) |   |
| **Actions to complete prior to cancellation (Clause 10.3)** |
| Applicant is informed of intent to cancel, is informed of their obligations and acknowledges the decision |   |
| IECEx secretariat is informed of cancellation |   |
| Any issues arisen as a result of the suspension and that affect products in the field have been addressed |   |

1. (informative)

Example text for notification of applicant of certificate suspension/cancellation
	1. Text to be used where certificate suspension is not due to non-conforming product

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

[INSERT LIST OF CERTIFICATES HERE, INCLUDING QAR IF APPLICABLE]

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

1. Website
2. Marketing material (data sheets, sales brochures, sales catalogues), as necessary
3. Product labelling
4. 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,

Our recent correspondence of our intentions to suspend/cancel the certificate/s of conformity listed below

* 1. Text to be used where certificate suspension is due to non-conforming product

The following text is supplementary to the text in B.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 cancelled and further action to rectify the issue of non-conforming products in the field may be taken.

1. (informative)

Example text for notification of applicant of certificate reinstatement or cancellation
	1. Reinstatement of certificate/s

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

[INSERT LIST OF CERTIFICATES HERE, INCLUDING QAR IF APPLICABLE]

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

1. Website
2. Marketing material (data sheets, sales brochures, sales catalogues)
3. Product labelling
4. Packaging
	1. Cancellation of certification

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

[INSERT LIST OF CERTIFICATES HERE, INCLUDING QAR IF APPLICABLE]

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