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1 Area of application

The certification program at hand applies to the certification of systems in the scope of application of Statutory Instrument 2016 No. 1107 as amended.

2 Certification procedure

2.1 Selection - Evaluation step I

1. Has a written application for examination / certification been submitted to the IBExU® UK? (The application forms / forms can be found on www.ibexu.uk in the respective service sectors.)
2. Has the requested scope of audit / certification (incl. relevant Designated Standards etc.) been clearly defined?
3. Are the products of the system requested for certification covered by the scope of the IBExU UK Ltd. (hereinafter referred to as “IBExU® UK”)?
4. Does the system for which a certification was applied for fall within the scope of application of
 - Statutory Instrument 2016 No. 1107 as amended?

IBExU® UK is entitled to reject an order. The applicant shall be informed about the rejection in writing.

If IBExU® UK accepts an order, a contract is only concluded with the order confirmation sent by the IBExU® UK.

The general terms and conditions and the general terms of contract published on www.ibexu.uk/general-terms apply.

2.2 Check of prerequisites - Evaluation step II

1. Have the required documents been submitted
 - in English and
 - in an adequate format?

Do they document completely the implementation of the scope of audit / certification applied for?

The general terms and conditions and the general terms of contract published on www.ibexu.uk/general-terms apply.

2.3 Evaluation of documents - Evaluation step I

1. Do the documents meet the applicable requirements?

IBExU® UK will inform the customer, if the documents do not meet the applicable requirements. The customer has the right to correct documents or to cancel the order. IBExU® UK does not make any revisions or amendments of documents.

Corrections are not part of the original order, they are charged according to the expenses incurred by further reviews. A review of corrections starts from the time when the customer submits further documents to the original order.

A customer has to inform the IBExU® UK in writing, if he has decided to cancel an order. The termination of an order will be confirmed by the IBExU® UK in writing.

Applicable requirements

The applicable requirements are due to the scope of audit / certification applied for. According to the scope of audit / certification, the following regulations are consulted in particular, but not limited to, for the assessment:

- Statutory Instrument 2016 No. 1107 as amended
- in conjunction with:
- ISO/IEC 80079-34
 - the Designated Standards concerning the products of the system applied for

2.4 Evaluation of processes - Evaluation step II

The customer receives an audit plan from IBExU® UK containing the basic data of the audit to be carried out. The customer is obliged to grant the auditors and, in individual cases, their observers access to the respective departments within the usual business / production hours, to provide them with the required documents and to participate actively in the actual audit.

1. Do the documents and business / production processes comply?
2. Do the business / production processes meet the applicable requirements?

IBExU® UK will inform the customer, if the processes do not meet the applicable requirements. The customer has the right to make corrections or to cancel the order. IBExU® UK does not make any revisions or amendments of the documents.

Corrections are not part of the original order, they are charged according to the expenditure for review and, if necessary, for auditing. A review of corrections starts from the time when the customer submits further documents to the original order.

The customer has to inform the IBExU® UK in writing, if he has decided to cancel the order. The termination of an order will be confirmed by the IBExU® UK in writing.

If both the documents and the processes meet the applicable requirements, IBExU® UK will prepare a report including a recommendation for certification.

Applicable requirements

The applicable requirements are due to the scope of audit / certification applied for. According to the scope of audit / certification, the following regulations are consulted in particular, but not limited to, for the assessment:

- Statutory Instrument 2016 No. 1107 as amended
- in conjunction with:
- ISO/IEC 80079-34
 - the Designated Standards concerning the products of the system applied for

Observers

Observers can be employees of the IBExU® UK (internal observers) as well as employees of the respective notifying authority (BEIS) or the body issuing the accreditation (UKAS). The assignment

of external observers depends on the scope of application applied for by the customer. The auditor must inform the customer in advance about the participation of one or more observers. IBEXU® UK will bear the expenditure arising by the participating observers.

2.5 Decision on certification

After the assessment ([2.4](#)), the certification will be decided upon.

After an assessment ([2.4](#)) with positive result, the certification is granted, maintained and / or extended according to the requested scope of certification.

However, depending on the result of the assessment ([2.4](#)), the certification may also be limited, suspended and / or withdrawn.

The general terms and conditions and the general terms of contract published on www.ibexu.uk/general-terms apply.

2.6 Documentation of certification

After a positive decision on certification ([2.5](#)), the customer will receive an official confirmation of conformity. This confirmation is usually given in form of a report as well as a corresponding conformity document.

The general terms and conditions and the general terms of contract published on www.ibexu.uk/general-terms apply. IBEXU® UK is entitled to suspend, refuse or restrict a conformity document, if

1. the holder of the certificate no longer fulfills the obligations arising from the certification program or from the contract concluded with the IBEXU® UK,
2. it was noticed that the holder of the certification document has deceived or attempted to deceive the IBEXU® UK or its representatives,
3. in particular the sign of conformity or the conformity document are used for a misleading or other inadmissible advertising,
4. the sign of conformity or the conformity document is misused,
5. the legal regulations for marketing are not observed,
6. the health and safety requirements have changed or relevant changes have occurred in the application of draft standards compared to the adopted standard with regard to the standardized requirements, unless it has been determined by a chargeable verification that the product meets the changed requirements
7. the conformity document is used for products or areas for which it has not been issued
8. defects are subsequently found in the products which were not identified during the inspection and which were not remedied within the specified period despite a written request by the approved body, or facts otherwise become known which would have prevented a certificate from being issued
9. the legal basis for the certification of a product is no longer given
10. in the case of QA-systems, the requirements on which the assessment was based have changed, taking into account transitional periods, unless it has been established by means of subsequent assessment, for which a charge is made, that the QA-system complies with the changed requirements

11. in the case of QA-systems, the certificate is used for operating areas for which it was not issued
12. defects are subsequently discovered in the QA-system that were not identified during the assessment, or facts otherwise become known that conflict with the issuance of a certificate.

2.7 Surveillance - Evaluation step III

In order to supervise the continued suitability of the certified system, one or two surveillance audits will be carried out within the duration of validity of the issued conformity document. In justified cases more surveillance audits can be carried out. The frequency of surveillance audits depends on the respective system type (type A - the system is certified in accordance with ISO 9001 / type B - the system is not certified in accordance with ISO 9001). For type A, the surveillance audit must be carried out after max. 18 months. For type B, it must be carried out after max. 12 months.

The surveillance audits shall include at least the steps [2.4](#) and [2.5](#).

3 Re-certification procedure

In order to prove the continued suitability of the certified system beyond the validity of the conformity document issued for a limited period of time and thus to maintain the certification of the system, a recertification procedure has to be carried out. The recertification procedure shall be applied for by the holder of the conformity document. The application should be submitted in time so that the recertification audit can be carried out three months prior to the expiry of the present conformity document. This gives the customer the possibility to process any deviations before the expiry of the certification.

If it is not possible to conclude a recertification procedure before the expiry of the temporary conformity document, the monitoring of each individual product (e.g. in accordance with Module F) must be initiated as soon as its validity expires. If the recertification audit can only be carried out after the expiry of the validity of the temporary conformity document, the procedure shall be carried out as an initial certification procedure.

The recertification procedure shall include at least the steps [2.1](#) to [2.7](#).

4 Place of performance

IBEXU® UK located in

IBEXU® UK Ltd.
Bristol Road South · Regus Park House
Birmingham · B45 9AH | United Kingdom

is responsible for performing the steps described in [2](#). However, these steps are subcontracted or contracted (with exception of steps [2.5](#) and [2.6](#)) and performed at the subcontractor's or contractor's registered office.

The steps [2.4](#) and [2.7](#) are performed in the divisions of the customer according to the scope of audit / certification applied for.

5 Subcontracting

IBEXU® UK is entitled to subcontract (partial) examinations. Subcontracts are only concluded with authorities that are equivalent to the IBEXU® UK and only after consultation with the customer.

The expenses incurring by subcontracting will separately be listed and invoiced to the customer.

6 Use of conformity documents and signs of conformity

1. Reports and conformity documents may only be used unchanged, in the full wording and with indication of the date of issue.
2. In accordance with the applicable requirements, the holder of a conformity document is entitled and obliged to affix the sign of conformity on the products complying with the tested models as specified in the conformity document.
3. Without any consultation with the holder of a conformity document, the IBEXU® UK is entitled to inform other equivalent bodies about issued conformity documents.

7 Holders of conformity documents - Obligation to provide information

7.1 Changes

The general terms and conditions and the general terms of contract published on www.ibexu.uk/general-terms apply. The holder of a conformity document (usually the customer) has to inform the IBEXU® UK about any essential change planned in the company, for ex-ample, changes in the company name, owners, location, locations of production sites, etc.

IBEXU® UK checks each case individually and then decides whether:

- a new issue is released
- re-assessment is necessary
- a new certificate is necessary

After review and evaluation of the indicated changes, the IBEXU® UK will take a decision on necessity of performance of an additional audit and on the certification (2.5). The customer will be informed about the decision. Depending on decision, the customer can be informed by means of a conformity document (2.6).

The expenses incurring in the context of the mentioned activities will be invoiced to the customer.

7.2 Objections

Holders of conformity documents must inform the IBEXU® UK immediately and without being asked about all objections concerning the maintenance of conformity of manufactured products with the respective applicable requirements. Holders of conformity documents shall keep records of all objections, the remediation of objections as well as the future avoidance. These records shall be made available to the IBEXU® UK.

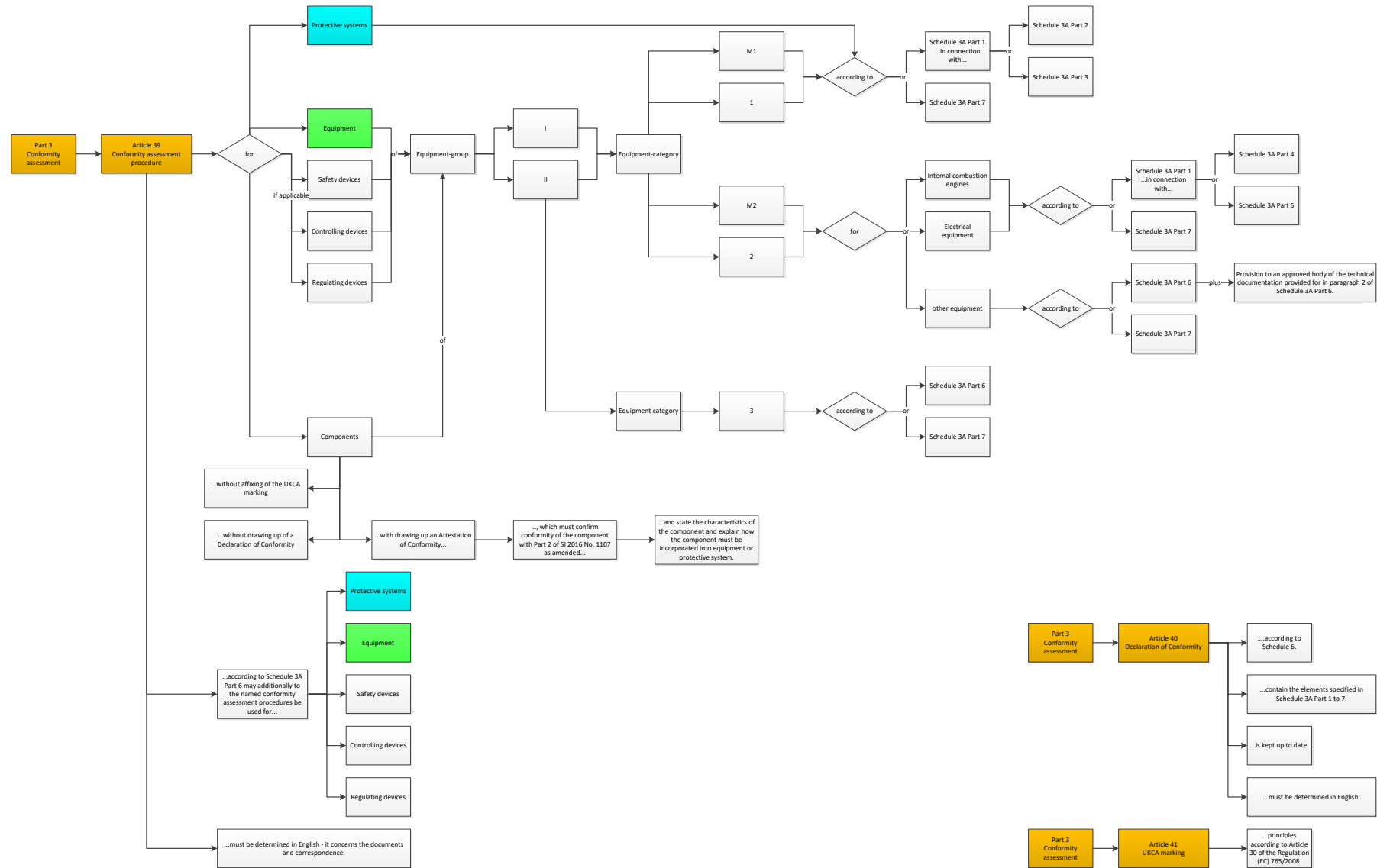
8 Complaints and appeals

The general terms and conditions and the general terms of contract published on www.ibexu.uk/general-terms apply.

If no agreement is reached on a complaint, an arbitration procedure may be conducted by another authority that is equivalent to the IBEXU® UK. IBEXU® UK shall bear the costs of the arbitration procedure, if a complaint was justified. If a complaint was unfounded, the customer shall bear the costs of the arbitration procedure.

If no agreement about a complaint can be reached, it will be presented to the mechanism to save the neutrality. The mechanism to save the neutrality which comprises various interested parties will process the appeal and inform both the IBEXU® UK and the customer about the decision taken. In addition, a representative of the mechanism to save the neutrality will inform the respective notified authority (BEIS).

I Annex



SI 2016 No. 1107 Designation Schedule 3A Part		Description				
1	Type examination	- is a	(the first) part of a	conformity assessment procedure	(a second part is required)	
		- involvement of an approved body is			required	
		- approved body examines the technical design of a product and verifies and attest that the technical design of the product meets the requirements of the Regulations that apply to it				
2	Conformity to type based on quality assurance of the production process	- is a	(the second) part of a	conformity assessment procedure		
		- involvement of an approved body is			required	
		- manufacturer fulfils the obligations for:	a) manufacturing, c) UK marking, declaration of conformity and attestation of conformity	and ensures and declares that the products concerned		are in conformity with the type described in the Type examination certificate and satisfy the requirements of the Regulations that apply for them
3	Conformity to type based on product verification	- is a	(the second) part of a	conformity assessment procedure		
		- involvement of an approved body is			required	
		- manufacturer fulfils the obligations for:	a) manufacturing, c) UK marking, declaration of conformity and attestation of conformity	and ensures and declares that the products concerned	, which have been subject to the provision of verification by an approved body,	are in conformity with the type described in the Type examination certificate and satisfy the requirements of the Regulations that apply for them

SI 2016 No. 1107 Schedule 3A Part	Designation	Description				
4	Conformity to type based on internal production control plus supervised product testing	- is a	(the second) part of a	conformity assessment procedure		
		- involvement of an approved body is			required	
		- manufacturer fulfils the obligations for:	a) manufacturing, b) product checks, c) UK marking, declaration of conformity and attestation of conformity	and ensures and declares that the products concerned		are in conformity with the type described in the Type examination certificate and satisfy the requirements of the Regulations that apply for them
5	Conformity to type based on product quality assurance	- is a	(the second) part of a	conformity assessment procedure		
		- involvement of an approved body is			required	
		- manufacturer fulfils the obligations for:	a) manufacturing, c) UK marking, declaration of conformity and attestation of conformity	and ensures and declares that the products concerned		are in conformity with the type described in the Type examination certificate and satisfy the requirements of the Regulations that apply for them
6	Internal production control	- is a	complete	conformity assessment procedure	(no further part is required)	
		- involvement of an approved body is			required	, if applicable

SI 2016 No. 1107 Schedule 3A Part	Designation	Description				
		- manufacturer fulfils the obligations for:	a) technical documentation, b) manufacturing c) UK marking, declaration of conformity and attestation of conformity	and ensures and declares that the products concerned		satisfy the requirements of the Regulations that apply for them
7	Conformity based on unit verification	- is a	complete	conformity assessment procedure		(no further part is required)
		- involvement of an approved body is			required	
		- manufacturer fulfils the obligations for:	a) technical documentation, b) manufacturing c) UK marking, declaration of conformity and attestation of conformity	and ensures and declares that <u>the product</u> concerned	, which has been subject to verification by an approved body,	<u>is</u> in conformity with the requirements of the Regulations that apply for them