

OPAC EN14399-00

Operating Procedure for the Attestation of Conformity to EN14399 Revision 00

Approved by BT3 on 20100323, by Board of directors on 20100618

**Operating Procedure
for the Attestation of Conformity of
High-strength structural bolting assemblies for preloading
in compliance with Annex ZA of EN 14399-1**

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Draft not yet approved by the Board

1 Scope of the document

This document specifies the procedure to be applied for the attestation of conformity of high-strength structural bolting assemblies for preloading in compliance with Annex ZA of EN 14399-1.

It applies to all products covered by EN14399-2 to -6 and to other products related in other standards whose application is made in accordance with the Constructions Products Directive (CPD - 89/106/EEC).

The rules underlying the present operating procedure comply with different official papers issued by the European Commission whose exact reference is quoted.

2 The Attestation of Conformity Systems in the field of the CPD

Guidance Paper K goes into detail on the various attestation of conformity (AoC) systems within the context of the implementation of the CPD. It also addresses the relation between the AoC systems and the Notified Bodies. It clarifies the role of the relevant Notified Body/Bodies under the different AoC systems.

2.1 Underlying principles

The CPD identifies a complete set of attestation of conformity systems including all the actors with their respective roles and tasks. Voluntary European or international standards [ISO 9000 series, EN 45000 series] can be used as a starting point where appropriate but are not obligatory.

The producer is fully responsible for the attestation that products are in conformity with the requirements of a technical specification. The involvement of a third party, even to provide an EC certificate of conformity, does not relieve the producer of any of his obligations. However, under the CPD, responsibility for specific actions is given to a third party for all systems of attestation of conformity (AoC) except system 4.

Whether or not there is third party intervention in attestation of conformity, all of the tests and procedures required by the CPD and the technical specifications must be performed and documented correctly. The documentation shall be available for notifying authorities and surveillance authorities where relevant.

2.2 Methods of control of conformity

2.2.1 Initial Type-Testing (ITT)

Initial type-testing of the product by the manufacturer or a notified body is applicable to all AoC systems. An Initial Type test is the complete set of tests or other procedures described in the harmonised technical specification, determining the performance of samples of products representative of the product type. An ITT verifies that a product complies with the harmonised technical specification. It defines the performance of all harmonised characteristics to be declared. Depending on the limitations of intended uses chosen by, and the specific markets envisaged by the manufacturer, the scope of the ITT could be limited to those applicable to the uses foreseen. A product type may cover several versions of the product, provided that the differences between the versions do not affect the level of safety and the other requirements concerning the performance of the product. An initial type test is not an assessment of the fitness for use of a product. The ITT is rather a determination of the performance of a product, on the basis of tests or other procedures described in the technical specifications. The ITT is only one element which determines whether or not a product can be attested to be in conformity with a technical specification. However, the ITT does play a fundamental role under the CPD as it provides the reference for the declared performance of the product.

2.2.2 Audit-testing

Audit-testing of samples taken at the factory, on the open market or on a construction site is made by the manufacturer or a notified body. Commission Decisions generally limit audit testing by Notified Bodies, under the attestation of conformity procedures, to the premises of the manufacturer or his authorised representative. A proper "audit-test" assumes that:

- The construction product is tested in accordance with the test methods specified in the technical specification and the initial type test.
- The test results are compared with the declared performances of the product derived from the initial type test.
- A test report is delivered, confirming that the findings are in conformity with the technical specifications, the ITT and FPC provisions.

2.2.3 Factory Production Control (FPC)

In the CPD, factory production control means the permanent internal control of production exercised by the manufacturer. Normally this includes testing by the manufacturer, to assure compliance of the manufactured products with the declared performances of the initial type test.

2.3 Systems of conformity attestation

The systems of conformity attestation include:

- Certification of the conformity of the product by a notified certification body on the basis of different tasks for the manufacturer and notified bodies (Systems 1 and 1+).
- Declaration of conformity of the product by the manufacturer (Systems 2, 2+,3 and 4)

2.4 System 2+

2.4.1 Tasks and basis for CE marking

According to system 2+, in force according to EN14399 for high-strength structural bolting assemblies for preloading, the different tasks are defined as follows:

- Task for manufacturer
 - Initial type of testing of product
 - Factory production control
 - Testing of samples according to prescribed test plan
- Task for notified body
 - Certification of factory production control on basis of initial inspection
 - Initial inspection
 - Continuous surveillance, assessment and approval of production control
- Basis for CE marking
 - Manufacturer's conformity Declaration.
 - Certification of factory production control.

2.4.2 Specificities

The result of the actions of the notified body under this first possibility is in all cases a factory production control certificate. The only difference between the commonly used terms "system 2" and "system 2+" are that whereas both 2 and 2+ involve assessment of Factory Production Control, system 2+ also involves surveillance.

The certification of factory production control (FPC) refers to an evaluation of the permanent internal control of production exercised by the producer (to enable achievement of the required product characteristics to be checked). Thus, both initial inspection and continuous surveillance are general activities relating to a particular production facility, in order to demonstrate that the FPC is in conformity with the requirements of the technical specification and the CPD.

Given the general character of FPC certification, there is no one-to-one relationship with the individual product characteristics, even if some aspects of a product's performance may warrant particular attention (to be specified in the technical specifications if this is the case). Hence, the allocation of tasks to the notified body or the producer on the basis of individual product characteristics does not have any practical value. The assessment of FPC concerns all of the elements, requirements and provisions adopted by the producer to fulfil his obligations under the CPD.

Certification of FPC does not involve assessment of the overall conformity of a product with a technical specification - this remains the responsibility of the producer.

3 Main Issues in Annex ZA of EN14399-1

3.1 Clauses of this European Standard addressing the provisions of EU Construction Products Directive

The European Standard has been prepared under mandate M/120 "Structural metallic products and ancillaries" given to CEN by the European Commission and the European Free Trade Association. The clauses of the EN 14399, shown hereunder meet requirements of the mandate given under the EU Construction Products Directive. Compliance with these clauses confers a presumption of fitness of the construction products covered by EN 14399 for their intended use(s).

Characteristic for the mandate	Requirement clause(s)
Bolts	
Tolerances on dimensions, form and position	4.4.2
Percent elongation after fracture	4.4.3
Minimum tensile strength Stress at 0,2 % non-proportional elongation Stress under proof load Strength under wedge loading Hardness Impact strength	4.4.3
Friction coefficient (<i>k</i> -class)	4.4.4
Release of dangerous substances	4.2.1
Durability	4.5
Nuts	
Tolerances on dimensions, form and position	4.4.2
Stress under proof load Hardness	4.4.3
Release of dangerous substances	4.2.1
Durability	4.5
Washers	
Tolerances on dimensions, form and position	4.4.2
Hardness	4.4.3
Release of dangerous substances	4.2.1
Durability	4.5
Assemblies	
Suitability of assembly for preloading ($F_{bi\ max}$, $\Delta\theta_2$, <i>k</i> -class)	4.4.4
Durability	4.5

3.2 Systems for the attestation of conformity of products

3.2.1 General

For products and intended uses listed below, the system for attestation of conformity shall be as follows:

3.2.1.1 Products

- structural connectors

3.2.1.2 Intended uses

Use in structural metallic works

3.2.1.3 Attestation of conformity system

System **2+**: according to CPD Annex III.2.(ii), First possibility, including certification of the factory production control by an approved body on the basis of its initial inspection of factory and of factory production control as well as of continuous surveillance, assessment and approval of factory production control.

3.2.2 Steps of conformity control

The steps of control of conformity are set out hereunder.

Declaration of conformity of the product by the manufacturer
Initial type testing of the product by the manufacturer;
Testing of samples taken at the factory in accordance with a prescribed test plan by the manufacturer;
Factory production control by the manufacturer;
Initial inspection of factory and factory production control by an approved body;
Continuous surveillance, judgement and assessment of the factory production control by an approved body.

3.2.2.1 Initial type testing by the manufacturer

An initial type testing program shall be carried out under the sole responsibility of the manufacturer of the products before they are first placed on the market. Such a program shall be carried out in each case for all the products which a manufacturer places on the market in accordance with EN 14399 or other related standards. For the purposes of testing, the products may be grouped into families, where it is considered that the selected properties are common to all the products within that family.

Initial type testing shall be performed on first use of EN 14399 for products being put onto the market and:

- at the beginning of the production of a new or modified assembly design, raw material or source or supplier of the raw material or the components;
- at the beginning of a new or modified method of production.

In case of type testing on products for which initial type testing in accordance with EN 14399 was already performed, type testing may be reduced:

- if it has been established that the performance characteristics compared with the already tested products have not been affected, or
- in accordance with the rules for grouping and/or direct application or application by extrapolation of test results.

The assessment of the following characteristics is required:

- Bolts
 - Dimensions and tolerances
 - Percent elongation after fracture
 - Minimum tensile strength
 - Stress at 0,2 % non-proportional elongation
 - Stress under proof loading
 - Strength under wedge loading
 - Hardness
 - Impact strength
- Nuts
 - Dimensions and tolerances
 - Stress under proof loading
 - Hardness
- Washers
 - Dimensions and tolerances
 - Hardness
- Assemblies
 - Suitability for preloading

3.2.2.1.1 Initial type testing program

The initial type testing program comprises:

- Definition of the characteristics to be appraised,
- Test method,
- Number of tests.

It is described in the relevant Table of the EN 14399-1 standard.

The results of all type tests shall be recorded and held by the manufacturer for at least 10 years.

3.2.2.1.2 Use of historical data

Tests previously performed on the same products in accordance with the provisions of this document (same characteristic(s), test method, sampling procedure, system of attestation of conformity, etc.) may be taken into account.

3.2.2.2 Testing of samples taken at the factory by the manufacturer

As a periodic audit, the testing of samples taken at the factory by the manufacturer in accordance with a prescribed plan as specified by EN 14399-1 shall be the means of evaluation of conformity of the product delivered in accordance with the relevant part of EN 14399.

The following minimum test frequencies apply:

- First year of implementation of this standard: Twice
- Following years: Once a year in the absence of any major non-conformances
- If a failure occurs repeat testing at a frequency which will avoid defective products being placed on the market and subsequently: Twice a year until a complete year has been achieved without major non-conformances

If required, the report of such testing as carried out by the manufacturer shall be an inspection document **3.1.B** in accordance with EN 10204.

3.2.2.3 Factory production control

The manufacturer shall operate a factory production control system. In the Construction Products Directive, factory production control means the permanent internal control of production exercised by the manufacturer. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic manner in the form of written policies and procedures.

The FPC system shall consist of written procedures (works' manual), regular inspections and tests and/or assessments and the use of the results to control raw and other incoming materials or components, equipment, the production process and the product.

An FPC system conforming with the requirements of EN ISO 9001, and made product specific to the requirements of this document, is considered to satisfy the above requirements.

The results of inspections, tests or assessments requiring action shall be recorded, as shall any action taken. The action to be taken when control values or criteria are not met shall be recorded and retained for the period specified in the manufacturer's FPC procedures.

The responsibility, authority and the relationship between personnel that manages, performs or verifies work affecting product conformity, shall be defined. This applies in particular to personnel that

need to initiate actions preventing product non-conformities from occurring, actions in case of non-conformities and to identify and register product conformity problems.

All measuring and testing equipment shall be calibrated or verified and regularly inspected according to documented procedures, frequencies and criteria. All equipment used in the manufacturing process shall be regularly inspected and maintained to ensure use, wear or failure does not cause inconsistency in the manufacturing process.

Inspections and maintenance shall be carried out and recorded in accordance with the manufacturer's written procedures and the records retained for the period defined in the manufacturer's FPC procedures.

The factory production control system shall document the various stages in the design of the products, identify the checking procedure and those individuals responsible for all stages of design. During the design process itself, a record shall be kept of all checks, their results, and any corrective actions taken. This record shall be sufficiently detailed and accurate to demonstrate that all stages of the design phase, and all checks, have been carried out satisfactorily.

The specifications of all incoming raw materials and components shall be documented, as shall the inspection scheme for ensuring their conformity. In case supplied assembly components are used, the attestation of conformity level should at least coincide with that of the assembly. If this is not the case, the inspection scheme should be raised to obtain that level.

Characteristics, which cannot be controlled on the finished product, shall be controlled by in-process control.

The manufacturer shall establish procedures to ensure that the production tolerances allow for the product performances to be in conformity with the declared values, derived from initial type testing.

The manufacturer shall record the results of the tests specified in the relevant Table of EN 14399-1:

- Bolts
 - Strength under wedge loading or hardness
- Nuts
 - Hardness
- Washers
 - Hardness
- Assembly
 - Suitability for preloading

These records shall at least include the following information:

- identification of the product and assembly tested;
- the date of sampling and testing;
- the test methods performed;
- the test results.

Individual components and assemblies shall be identifiable and traceable with regard to their production origin. The manufacturer shall have written procedures ensuring that processes related to affixing traceability codes and/or markings are inspected regularly.

The manufacturer shall have written procedures, which specify how non-conforming products shall be dealt with. Any such events shall be recorded as they occur and these records shall be kept for the period defined in the manufacturer's written procedures.

The manufacturer shall have written procedures providing methods of product handling and shall provide suitable storage areas preventing damages or deterioration.

The factory production control system shall be certified by a notified body.

3.3 EC certificate and declaration of conformity

The manufacturer or his agent established in the European Economic Area (EEA), shall prepare and retain a declaration of conformity, which authorises the affixing of the CE marking. This declaration shall include:

- name and address of the manufacturer, or his authorised representative established in the EEA, and the place of production;
- description of the product (type, identification, use ...), and a copy of the information accompanying the CE marking;
- provisions to which the product conforms (e.g. Annex ZA of EN14399-1);
- particular conditions applicable to the use of the product [if necessary];
- the number of the accompanying factory production control certificate;
- name of, and position held by, the person empowered to sign the declaration on behalf of the manufacturer or his authorized representative.

The declaration shall be accompanied by a factory production control certificate, drawn up by the notified body, which shall contain in addition to the information above, the following:

- name and address of the notified body;
- the number of the factory production control certificate;
- conditions and period of validity of the certificate, where applicable;

- name of, and position held by, the person empowered to sign the certificate.

This declaration and certificate shall be made available upon request and presented in the languages of the member state of use of the product.

3.4 CE marking and labelling

3.4.1 Content

The CE marking shall be in accordance with Directive 93/68/EEC and be placed on the accompanying commercial documents (inspection document). The CE marking consists of the letters "CE" in the specified form and shall be accompanied by the following information:

- identification number of the notified body;
- name or identifying mark of the manufacturer of the assemblies;
- the last two digits of the year of CE marking;
- the number of the certificate of conformity with regard to the factory production control system;
- the reference to this document (EN 14399-1);
- the product designation by reference to the relevant parts of this document;
- the k -class with the following information, as relevant:
 - K0: NPD (No performance determined)
 - K1: range of individual test values k_i
 - K2: Mean value of the k -factor (k_m), coefficient of variation of the k -factor (V_k).


3.4.2 Important notes

The product designation includes the property classes of bolts and nuts, which specify the mechanical and physical properties of these products and are defined in EN ISO 898-1 and in EN 20898-2 respectively.

The "No performance determined" (NPD) option may not be used where the characteristic is subject to a threshold level.

Otherwise, the NPD option may be used when and where the characteristic, for a given intended use, is no subject to regulatory requirements in the Member state of destination.

3.4.3 Example for CE marking:


Any Co Ltd. PO Box 23, B1070 02 Number XXX/2003 of the EC certificate 1148 number of OCAB-OCBS as notified body
EN 14399-1 Bolt assembly for preloading for use in accordance with a defined k-class Bolt EN 14399-3 — M16 × 80 — 10.9 — HR Nut EN 14399-3 — M16 — 10 — HR Washer EN 14399-6 — 16 k-class: K2: $k_m = 0,13$, $V_k = 0,06$

In addition to any specific information relating to dangerous substances shown above, the product should also be accompanied, when and where required and in the appropriate form, by documentation listing any other legislation on dangerous substances for which compliance is claimed, together with any information required by that legislation.

4 Requirements for Factory Production Control

4.1 General comments

The manufacturer is responsible for organising the effective implementation of the factory production control system. Tasks and responsibilities in the production control organisation should be documented and this documentation should be kept up-to-date. In each factory the manufacturer may delegate the action to a person having the necessary authority to:

- identify procedures to demonstrate conformity of the product at appropriate stages;
- identify and record any instance of non-conformity;
- identify procedures to correct instances of non conformity.

The manufacturer should draw up and keep up-to-date documents defining the factory production control which he applies. The manufacturer's documentation and procedures should be appropriate to the product and manufacturing process. All FPC systems should achieve an appropriate level of confidence in the conformity of the product. This involves:

- the preparation of documented procedures and instructions relating to factory production control operations, in accordance with the requirements of the reference technical specification;
- the effective implementation of these procedures and instructions;
- the recording of these operations and their results;
- the use of these results to correct any deviations, repair the effects of such deviations, treat any resulting instances of non-conformity and, if necessary, revise the FPC to rectify the cause of non-conformity.

Production control operations include some or all of the following operations:

- the specification and verification of raw materials and constituents;
- the controls and tests to be carried out during manufacture according to a frequency laid down;
- the verifications and tests to be carried out on finished products according to a frequency which may be laid down in the technical specifications and adapted to the product and its conditions of manufacture.

4.2 Verifications and tests

The manufacturer must have or have available the installations, equipment and personnel which enable him to carry out the necessary verifications and tests. He may, as may his agent, meet this requirement by concluding a subcontracting agreement with one or more organisations or persons having the necessary skills and equipment.

The manufacturer must calibrate or verify and maintain the control, measuring or test equipment in good operating condition, whether or not it belongs to him, with a view to demonstrating conformity of the product with its technical specification. The equipment must be used in conformity with the specification or the test reference system to which the specification refers.

4.2.1 Monitoring of conformity

If necessary, monitoring is carried out of the conformity of intermediate states of the product and at the main stages of its production. This monitoring of conformity focuses where necessary on the product throughout the process of manufacture, so that only products having passed the scheduled intermediate controls and tests are dispatched.

4.2.1.1 Tests

Tests should be in accordance with the test plan and be carried out in accordance with the methods indicated in the technical specification. These methods should generally be direct methods. It is however possible, in the case of certain characteristics, that the prescribed specification gives the possibility of using indirect test methods if a definite correlation or relationship can be established and if possible verified between specified characteristic X - the characteristic to be verified - and another

characteristic Y which is easier or safer to measure than characteristic X. Indirect test methods may be retained when available and appropriate.

4.2.1.2 Test Records

The manufacturer should establish and maintain records which provide evidence that the product has been tested. These records should show clearly whether the product has satisfied the defined acceptance criteria. Where the product fails to satisfy the acceptance measures, the provisions for non-conforming products should apply.

4.2.1.3 Treatment of products which do not conform.

If control or test results show that the product does not meet the requirements, for example if the statistical variation of test results exceeds the limits allowed by the technical specification, the necessary corrective action must immediately be taken. Products or batches not conforming must be isolated and properly identified. Once the fault has been corrected, the test or verification in question must be repeated. If products have been delivered before the results are available, a procedure and record should be maintained for notifying customers.

4.2.1.4 Recording of verifications and tests (manufacturer's register).

The results of factory production controls must be properly recorded in the manufacturer's register. The product description, date of manufacture, test method adopted, test results and acceptance criteria must be entered in the register under the signature of the person responsible for control who carried out the verification. With regard to any control result not meeting the requirements of the technical specification, the corrective measures taken to rectify the situation (e.g. a further test carried out, modification of manufacturing process, throwing away or putting right of product) must be indicated in the register.

4.2.2 Traceability

It is the manufacturer's, or his agent's, responsibility to keep full records of individual products or product batches, including their related manufacturing details and characteristics, and to keep records of to whom these products or batches were first sold. Individual products or batches of products and the related manufacturing details must be completely identifiable and retraceable. In certain cases, for example for bulk products, a rigorous traceability is not possible. The expression of the requirement in the relevant technical specifications should be realistically adapted keeping in view a traceability as complete as possible.

4.3 Contents of the technical specifications on products

Technical specifications specify in the appropriate chapters the elements and requirements either mandatory or informative referred to above. Everything comprising the necessary provisions of factory production control and the attestation of conformity adopted for the product to which the specification

relates has a mandatory character. Where possible, the elements mentioned and the requirements set out must be adapted or adaptable:

- to the particular features of the manufacturing processes. In particular, production control must be able to be adapted depending on the degree of automation of the manufacturing chain, adjustment devices, self adjustment, which manufacture may comprise.
- to the performance level the product is intended to have where the technical specification of the product provides for a range of performance levels and where the risk resulting from not achieving the intended performance varies with the level.

The adaptation procedures must be chosen in the interests of ensuring that the level of confidence obtained by the production control is effectively the same for all conceivable situations of manufacture.

4.4 Compliance with ISO 9000

The ISO 9000 series of standards is not a mandatory requirement in the framework of the Construction Products Directive and should not be included as such in harmonised technical specifications.

Manufacturers having an FPC system which complies with ISO 9000 and which addresses the requirements of the appropriate harmonised standard are recognised as satisfying the FPC requirements of the Directive.

5 Factory production control by the manufacturer

5.1 General requirements

The purpose of factory production control is to ensure that the bolting equipment are manufactured in a controlled way to meet all of the requirements of the relevant product specification standard. In order that a notified body can verify such a system it has to be documented in a structured way. This is carried out in a Works' quality manual supported and cross-referenced by a series of procedures, work instructions and other associated and relevant documents. These need to be clear, concise and adopt recommended good practices where applicable. The factory production control system may form part of a wider, integrated management system provided it can be demonstrated that all applicable EN 14399 requirements are addressed.

5.2 Works' quality manual

The manufacturer's documentation and procedures for factory production control shall be described in a Works' quality manual, which shall adequately describe, among other things:

- the quality aims and the organisational structure, responsibilities and powers of the management with regard to product quality and the means to monitor the achievement of the required product quality and the effective operation of the internal quality control;
- the manufacturing and quality control techniques, processes and systematic actions that will be used;
- the inspections and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out.

The Works' quality manual prepared by the manufacturer for each factory shall include an adequate system of documentation. The Works' quality manual shall address and document the procedures operated to ensure that the manufactured bolting equipment conform to the technical specifications. The manual may reference associated documents which provide further details of the autocontrol testing of samples and the internal quality control. For the purpose of this scheme, the term Works' quality manual shall be considered to include these associated documents.

In the case of an existing quality management system according to EN ISO 9000, the notified body may examine if the corresponding quality manual meets all the requirements of EN 14399 which are relevant to the factory production control of bolting equipment. Provided all the requirements are included, this quality manual may also be applied for product certification.

Guidelines

- The Works' quality manual is the fundamental document that describes the factory production control system operated by the bolting equipment factory. It should clearly state the scope of the factory production control system and must describe how each of the elements of the system are controlled and maintained.
- The Works' quality manual normally comprises a main document together with associated documents and technical procedures. All these documents are written in the current language of the factory's country.
- To ensure an effective factory production control system, there needs to be a well defined organisational structure within the bolting equipment factory, showing very clearly the lines of reporting and this is best achieved by one or more simple diagrams. The manual should list all personnel who can affect quality within the manufacturing process together with their job titles and refer to a description of their tasks and responsibilities within the quality function. These should pay particular attention to the level of authority to check, assess, verify and pass conforming product.
- There needs to be a quality plan for the production of conforming bolting equipment and whilst it must be recognised that the plan can take on one of many forms and include such things as process flow charts and control tables, it must show how each of the parts of the process are

connected. There must be a clear indication of where samples are taken and at what frequency, together with the tests to be applied. Targets and acceptability criteria should also be documented.

- In the case of an existing quality management system in accordance with ISO 9000 it should be clearly stated in the Works' quality manual that the system is also used for factory production control according to EN 14399 and the other relevant product specification standards.

5.3 Management systems

5.3.1 Quality policy statement

The Works' quality manual shall include a statement by management defining its quality policy, objectives and commitments to the attainment of product quality.

Guidelines

- The quality policy statement is a document signed normally by the managing director of the company or by the manager of the factory, depending on the organisation of the company, or by both. It should include the quality aims and its commitment to meeting the requirements of standards and/or of its customers and to ongoing improvement, both internally and externally. It should indicate approval of the factory production control system as outlined in the Works' quality manual and that it is mandatory.
- The system by which all personnel are informed of the quality policy should be documented. A route for feedback should be established to aid understanding of the policy.
- In the case of an existing quality management system in accordance with EN ISO 9000, the quality policy statement should include a commitment to the attainment of bolting equipment quality in relation to the relevant product specification standard.
- The Quality Policy should be reviewed periodically to ensure changes in aims are incorporated.

5.3.2 Management representative

The manufacturer shall appoint a management representative who, irrespective of other responsibilities, shall have defined authority and responsibility for ensuring that the requirements of EN 14399 for the evaluation of conformity are implemented and maintained.

Guidelines

The Management Representative should be clearly shown to have the necessary dedication, time and authority to ensure that bolting equipment continues to conform to the relevant product specification standard by the adoption of the requirements of the documented factory production control system. As he has the ultimate responsibility for the effective operation of factory production control his responsibilities should at least include maintenance of the Works' quality manual, the operation of process and autocontrol and the evaluation of the bolting equipment data to the relevant product specification standard requirements. Effective and unrestricted communication channels to other affected departments must be open to the management representative to discuss possible problems.

The authority and responsibility for the factory production control system and the quality assurance of bolting equipment are not necessarily held by the same person.

The Works' quality manual should state to whom the responsibility is transferred in the absence of the management representative.

5.3.3 Internal audits and management review

In order to ensure the continuing suitability and effectiveness of the Work's quality manual to meet the requirements of EN 14399, the manufacturer shall perform at least once per year:

- internal audits;
- a management review of the factory production control, taking into account records of the internal audits.

Guidelines

- For audits to be of value there needs to be evidence that non-conformities raised are progressed to a satisfactory conclusion and this must be assessed by management during the review. Reviews should be conducted to an established formal agenda by a management team and a record made of the findings, showing actions to be taken and relevant responsibilities. Reviews will need to take account of not only the internal audits but also of customer complaints.
- Audits need to be carried out at an established frequency, procedures and plan, by trained personnel independent of the area to be audited. It is essential that internal audits cover all aspects dealt with in the Works' quality manual, not forgetting compliance of bolting equipment constituents with standard requirements and in-process specifications.

5.3.4 Training

The Works' quality manual shall describe the measures taken to ensure that all the personnel involved in operations that can affect internal quality control and product quality have appropriate experience or training. Appropriate records shall be retained.

Guidelines

- The adequate training of all personnel engaged in quality related matters and forming part of the factory production control system is of prime importance. It ensures that the exact skills and level of understanding are achieved to allow tasks to be carried out correctly and efficiently.
- A training plan, covering all the relevant personnel should be available, listing the essential skills and education required for each element of the task/responsibility to be covered. These need to cover both technical skills and an understanding of the function and operation of quality systems. The training plan must be supported by management and be continuous. It should indicate the minimum educational level required for each role. Training can be external, as well as internal - details of these should be recorded.

- A separate training plan for new starters will be required to cover induction training.

5.4 System of documentation

5.4.1 Document control

The management representative shall be responsible for the control of all documents and data related to factory production control and to this scheme for the evaluation of conformity.

This control shall ensure that the appropriate issues of all documents are available at essential locations and that obsolete documents are withdrawn and that changes or modifications to any document are effectively introduced.

A master list shall be established to identify the current version of documents in order to prevent the use of non-applicable documents.

Guidelines

- The effectiveness of the factory production control system relies on the availability and use of correctly updated documents and data which include the Works' quality manual, procedures, operating instructions, technical specifications, plans, flowcharts, test methods and data records; this list is not exhaustive. A procedure must be available covering the issuing of amendments and updated documents. All documents should be listed, giving proper identification, issue status and approval, holders and locations and mode of disposal of previous issues. If previous issues are to be retained they must be suitably marked to indicate that they are obsolescent and withdrawn.
- The principles of the document control are the same as those of ISO 9000, which can therefore be used as guidelines.

5.4.2 Quality records

The manufacturer shall retain records of factory production control for at least the period required to comply with relevant legislation.

Guidelines

- All factory production control records should be kept for a minimum period of three years and the Works' quality manual will identify retention periods and location of all records. Factory production control records that relate directly to the finished bolting equipment should be retained for at least the period necessary to satisfy product liability legislation and for at least a period of ten years.
- All records must be legible, identifiable, retrievable and protected from damage, deterioration or loss. Where records have been transferred to electronic or optical storage media, suitable back up copies should be taken.

5.5 Internal quality control

5.5.1 Process control

4.2.1.1 General

The Works' quality manual shall describe the parameters for process planning, process control and testing, inspection, corrective action, verification, dispatch and the associated records.

Guidelines

- Process control should be designed to prevent non-conformities arising. This cannot be achieved by testing only. To ensure that bolting equipment complies with the relevant product specification standard, planning of the production process is required and should address the following:
 - A process flow description/diagram to illustrate the important production elements and show how each stage is interrelated.
 - Targets and control limits (and subsequent actions if these are not met for each process stage, including parameters that are not included in the product specification standard);
 - Method and frequency of data collecting and processing;
 - Adequate testing and control of intermediate products.

5.5.2 Composition of bolting equipment

The manufacturer shall establish documented procedures and appropriate test methods to ensure that the constituents meet the requirements of the relevant product specification standard and are suitable to enable bolting equipment to be produced meeting the technical specification.

The Works' quality manual shall describe the methods used by the manufacturer to ensure that the composition of the bolting equipment produced conforms to the relevant product specification standard, including appropriate test methods.

Guidelines

- Incoming supply should be assessed against a previously agreed specification and will generally involve sampling and testing. Procedures may include those to establish suitability of different sources of all constituents including additives.
- The target level values of all constituents should be specified and recorded.

5.5.3 Measuring and testing

5.5.3.1 Inspection, measuring and test equipment

The equipment for in-process inspection and testing shall be regularly checked and calibrated in accordance with the procedures and frequencies laid down in the Works' quality manual.

Guidelines

- All equipment should be uniquely identified and verified to a programme prescribed in the Works' quality manual. Equipment used to control and monitor standard properties should be checked and calibrated. Verification and calibration records should enable verification of the calibration status of the equipment and that out of specification or calibration should be marked "not for use" and isolated. Verification and calibration procedures should be documented.

5.5.3.2 Inspection and test status

Procedures for the inspection and test status through the stages of manufacture shall be detailed in the Works' quality manual.

Guidelines

- The quality system and procedures should ensure that all required inspections and tests are carried out. The system needs to provide a way of showing these have been done and the particular status of materials at each stage of the process. This is probably best achieved by the signing-off of results in the operating logbooks by the quality manager or his appointee, supported by designated storage areas for the various materials.

5.5.4 Handling, storage, packaging and delivery

The Works' quality manual shall describe the precautions taken for the protection of the quality of the bolting equipment while under the responsibility of the manufacturer. It shall include a description of the procedures used for stockholding. Delivery documentation shall allow traceability to the producing works.

Weighing equipment should be uniquely identified and calibrated to a prescribed programme, and should carry a corresponding calibration certificate.

5.5.5 Autocontrol testing of samples

5.5.5.1 Sampling and testing

The manufacturer shall operate a system of autocontrol testing for each certified bolting equipment. This system shall be used to demonstrate conformity to the requirements in the clause entitled "Conformity criteria" in the relevant product specification standard. The properties to be tested, the testing methods, the minimum frequency of autocontrol testing during routine testing and initial period testing and the conformity criteria shall be in accordance with the basic requirements given in the clause entitled "Conformity criteria" in the relevant product specification standard.

All test data shall be documented.

The reporting of test results may include the determination of the statistical characteristics for the relevant control period, i.e. number of test results, mean, minimum and maximum value, number of test results exceeding the characteristic and limit values, standard deviation and relevant fractiles.

5.5.6 Corrective action

The Works' quality manual shall document procedures for the review and adjustment of the factory production control in case of non-conformity.

The actions taken in the event of non-conformity shall be recorded in a report subject to inspection during the management review.

In the event of bolting equipment yielding a test result not conforming to the single result limit value conformity criteria specified in the relevant product specification standard, the manufacturer shall immediately determine the affected quantity, take appropriate action to prevent the dispatch of this quantity and inform the affected customer if such bolting equipment has been released. In addition, the manufacturer shall immediately determine the causes of such non-conformity, take corrective actions and undertake a review of all relevant factory production control procedures. All such actions and findings shall be appropriately recorded in a report subject to inspection during the management review.

The notified body may require to be kept informed of these actions and findings.

5.5.6.1 Measuring and test equipment for autocontrol testing

The equipment used for autocontrol testing shall be regularly checked and calibrated in accordance with procedures and frequencies laid down in the Works' quality manual. These procedures may include comparison of test results by proficiency testing with another laboratory designated in the Works' quality manual.

The Works' quality manual shall document procedures to ensure that all personnel involved in autocontrol testing have appropriate experience and training. Appropriate records shall be retained.

Guidelines

- All equipment used for conducting autocontrol testing should be uniquely identified and calibrated to a prescribed programme. Equipment and/or materials used as references during these calibrations need to be referenced to national or other recognised standards. Calibration records should indicate acceptable limits of use and enable verification of the calibration status of the equipment; that out of calibration should be marked "not for use" and isolated. Calibration procedures should be documented. If it is found necessary to adjust data following re-calibrations,

this should be documented and the notified body informed. This will be of importance in situations where adjustment produces a non-conformity.

- When an alternative test method is used for routine testing, results should be demonstrated by comparative testing to be equivalent to those of the reference test method.
- Appropriate actions should be taken when proficiency testing shows deviating results and these should be documented.

5.5.6.2 Quality records

The manufacturer shall retain records of the autocontrol test results and appropriate records on test equipment for at least the period required to comply with relevant legislation.

Guidelines

- Regulations valid in the country of manufacture define the minimum period of retention of all autocontrol and test equipment records and additionally this should be for at least a period of ten years. The Works' quality manual will identify retention periods and location of all records. The records must allow traceability of the autocontrol tests to the sampling points.
- All records must be legible, identifiable, retrievable and protected from damage, deterioration or loss. Where records have been transferred to electronic or optical storage media, suitable back up copies should be taken.

6 Tasks for the notified body

6.1 General

The notified body has responsibility for the functions of inspection and certification of the factory production control, inspection and testing. These functions may be carried out by one body or by more than one body. The inspection function may be carried out by an inspection body.

6.2 Surveillance, assessment and acceptance of the factory production control

6.2.1 Inspection tasks

The inspection tasks include surveillance, assessment and acceptance of the factory production control operated by the manufacturer. Inspection shall include checking that any major change in the Works' quality manual which is relevant to the factory production control of bolting equipment has been reported to the notified body by the manufacturer within one month of its implementation.

Inspection shall verify that the factory production control complies with the requirements of EN 14399 and has been carried out according to the Works' quality manual.

Guidelines

- The inspection team is normally composed of one or two persons, at least one of whom is technically competent in production and testing of bolting equipment. The inspection normally takes between one and two days depending on the complexity of the plant and the extent covered by the factory production control.
- The inspection body examines the documents and records, interviews the relevant personnel and inspects equipment (including equipment used in production and dispatch and in the laboratory). Emphasis is laid on all measures taken by the manufacturer to ensure the required product quality.
- Before leaving the factory, the inspectors normally give a copy of their main observations to the factory's quality manager. The inspection body may ask the manufacturer to comment and countersign this document before the inspectors leave the factory.

6.2.2 Frequency of inspections

The inspections shall normally be carried out once per year and the notified body shall inform the manufacturer in advance when an inspection is to be made.

Guidelines

- The inspection body, when delegated by the notified body, takes an initiative to agree with the manufacturer a date for the inspection.
- The notified body, at its own discretion, may request to be included in the distribution list of the controlled versions of the Works' quality manual. When the notified body is not on the distribution list it is appropriate that it requests an up-to-date copy of the Works' quality manual before the date of the inspection.
- The interval between two consecutive visits should be about 12 months; nevertheless, one inspection is to be made in every certified factory once per calendar year.

6.2.3 Reports

Following each inspection, a confidential report shall be prepared and sent to the manufacturer. The manufacturer shall, if appropriate, advise the notified body of any corrective actions taken or planned to be taken following receipt of the report.

The notified body shall then make a decision on its final assessment.

Guidelines

- The confidential report should not be restricted to discrepancies but should contain all relevant observations.
- The importance of any observations and the time within which corrections must be made should be clearly mentioned in the report.
- The report should be sent to the factory as soon as possible after the inspection, taking account of any needs for urgent action.

- Within a time specified in the inspection report, the manufacturer has to inform the notified body in writing about the corrective actions that he has taken or that he intends to take and the time for their implementation.

7 Initial type testing

7.1 Sampling

Samples shall be taken under the responsibility of the manufacturer according to the requirements of the relevant standard.

7.2 Properties and test methods

The mechanical, physical and chemical properties specified for testing in the clause entitled "Conformity criteria" in the relevant product specification standard shall be determined according to the indicated test methods.

Guidelines

- Other test methods than indicated may be used provided that it is demonstrated that this method yields equivalent results on the bolting equipment in question.

7.3 Evaluation of test results

The results obtained shall be evaluated by the manufacturer.

7.4 Reports

Following each evaluation of audit test results a confidential report shall be prepared without delay.

8 Initial inspection of the factory

8.1 Inspection of a new factory

In the case of a new factory, an initial inspection of the factory and the factory production control shall be made, based on information on the factory production control and the equipment to be used to produce bolting equipment. The inspection shall, among other things:

- verify that the Works' quality manual complies with the requirements;
- verify that the equipment used to produce and test the bolting equipment grades meet the criteria.

Guidelines

- The initial inspection of a new factory should include an examination of the whole Works' quality manual and all the related procedures.
- The initial inspection can take more than two days because of the necessity to examine if the Works' quality manual takes into account the totality of the points under reference.

8.2 Inspection of an existing factory

In the case of a new type of bolting equipment at an existing factory, information on any significant changes concerning the factory production control and the equipment, caused by the production of the new bolting equipment, shall be considered. This shall form the basis to decide, based on the importance of the changes to the Works' quality manual, whether a particular inspection is necessary. In this case any new equipment which has caused a major change in the Works' quality manual shall be inspected to verify that it meets the relevant criteria.

Guidelines

- In the case of a new type of bolting equipment at an existing factory, a new inspection of the factory is rarely necessary, except when fundamental changes have been necessary to produce the new type of bolting equipment. The notified body should decide if a new inspection is necessary, taking into account the modifications of the Works' quality manual and of the relevant procedures.

8.3 Criteria for the assessment of the production equipment

The inspection shall assess the suitability of the production equipment in relation to the Works' quality manual and in relation to providing the ability to meet the requirements of the relevant product specification standard. The following criteria shall be considered:

- Equipment shall be provided which is suitable for continuous mass production of bolting equipment, with sufficient accuracy to ensure that the requirements of the relevant product specification standard are met.
- Measures shall be taken to prevent the mixing of different bolting equipment grades and qualities during storage and delivery.

8.4 Criteria for the assessment of laboratories

The laboratory responsible for carrying out the tests required for internal quality control shall have at least the equipment needed to carry out the relevant tests indicated or referred to in the Works' quality manual.

The laboratory responsible for carrying out autocontrol testing shall have at least the equipment needed to carry out tests for the properties listed in the relevant product specification standard using the test methods indicated.

The laboratories shall demonstrate the ability to provide results within a time and in a manner suitable for the manufacturer's factory production control.

8.5 Reports

Following any initial inspection, a confidential report shall be prepared and a copy sent to the manufacturer.

9 Actions in the event of non-conformity

9.1 Actions to be taken by the manufacturer

The control of non-conforming bolting equipment and the corrective actions to be taken are the full responsibility of the manufacturer, who shall document the detailed procedures in the Works' quality manual.

Guidelines

- In the event of a non-conformity it is the responsibility of the manufacturer to take adequate measures in accordance with the relevant detailed procedures documented in the Works' quality manual.

10 Questionnaire regarding FPC

Questions are included in the Table reproduced hereunder.

Questions
For which product/product family a factory production control has been established and an initial inspection has been performed?
Did the methods of producing the products or the technical specification change since the latest continuous surveillance of the before-mentioned products/product family ?
If yes, did the producer adapt the documentation accordingly ?
Does the producer still apply a quality management system according to ISO 9000. which covers the factory production control of the certified products, and is that proved by a valid certificate ?
Is the machinery equipment still maintained correctly and regularly and is the relevant documentation in existence and updated ?
Is the personnel involved in the production still sufficiently qualified and trained to operate and maintain the machinery equipment ?
Have there been alterations in the staff since the initial or the last continuous surveillance ?
Are all processes and procedures of the production still recorded at regular intervals or continuously (automatically) ?
Have there been changes in the manner of recording or documenting since the initial or the last continuous surveillance ?
Does the producer still carry out for the certified products a traceable documentation of the

production process from the purchasing or delivery of the basic materials until the storage and the delivery of the finished products ?
Have the provisions for procurement of the basic materials and/or the suppliers been changed ?
Is an inspection of the incoming material still carried out and have there been any changes in the way and/or intervals ?
Are manner, extent and frequency of factory production control still in accordance with the provisions of the technical specification ?
Have any changes been made concerning test methods and/or testing equipment ?
Have appropriate comparable measurements been performed and documented ?
Do the findings of these tests still correlate with the test methods laid down in the technical specification for initial type testing or testing in the frame of the surveillance, respectively ?
Is the testing equipment still correctly maintained and calibrated to ensure constant accuracy of the tests performed during factory production control and surveillance ?
Does the producer still apply a documentation system which allows the detection of defects and deviations fast enough to identify and mark unambiguously products which are not in accordance with the product specification in order to eliminate them ?
Does the producer maintain a complete documentation of all incoming complaints (internal concerning the factory production control and external) concerning his certified products ?
Complaints with regard to certified products are considered in case of lacks of confidence concerning the conformity with the technical specification. Have appropriate measures for corrections also been introduced and are these measures documented ?
Have complaints received by the producer been reported to full extent to the certification body and to the supervising testing laboratory as well ?
Are the products duly marked with the CE-marking ?
Do the values measured during factory production control correspond with those values determined on products within the initial type-testing ?
Summary of the results by the inspection body and the measures to be taken for correction if necessary were applied.

11 Certification procedure

11.1 Manufacturers not holding an ISO 9000 certificate

11.1.1 Initial type testing of the product by the manufacturer

The manufacturer shall document in a metallurgical dossier the initial type testing of all related products according to the requirements of the technical specifications and the present operating procedure.

11.1.2 Testing of samples taken at the factory in accordance with a prescribed test plan by the manufacturer

The manufacturer shall document a prescribed test plan and demonstrate its right application to the approved body during initial inspection and continuous surveillance.

11.1.3 Factory production control by the manufacturer

The manufacturer shall document a factory production control and demonstrate its right application to the approved body during initial inspection and continuous surveillance.

11.1.4 Initial inspection of factory and factory production control by an approved body

The approved body shall evaluate:

- the capacity of the manufacturer to apply the foreseen factory production control,
- the capability of the foreseen factory production control and its fulfilment with the requirements of the present operating procedure,
- the fact that the factory production control really addresses the requirements of the EN 14399 standard,
- the right working of the factory production control as regards all its requirements,
- the capacity of the manufacturer of having the means to achieve the initial type testing.

11.1.5 Continuous surveillance, judgement and assessment of the factory production control by an approved body

The approved body shall evaluate:

- the capacity of the manufacturer to apply the foreseen factory production control,
- the capability of the foreseen factory production control and its fulfilment with the requirements of the present operating procedure,
- the fact that the factory production control really addresses the requirements of the EN 14399 standard,
- the right working of the factory production control as regards all its requirements.

11.2 Manufacturers already holding an ISO 9000 certificate

11.2.1 Initial type testing of the product by the manufacturer

The manufacturer shall document in a metallurgical dossier to be sent to the approved body before the initial inspection the initial type testing of all related products according to the requirements of the technical specifications.

11.2.2 Testing of samples taken at the factory in accordance with a prescribed test plan by the manufacturer

The manufacturer shall be deemed having already documented a prescribed test plan.

11.2.3 Factory production control by the manufacturer

The manufacturer shall compile in a metallurgical dossier to be sent to the approved body before the initial inspection the features of its factory production addressing the requirements of the EN 14399 standard. A copy of the ISO 9000 certificate will be included.

11.2.4 Initial inspection of factory and factory production control by an approved body

Prior to the initial inspection, the approved body shall evaluate the metallurgical dossier prepared by the manufacturer relating to initial type testing and factory production control and will have requested necessary complementary information.

The initial inspection shall be conducted after acceptance of the metallurgical dossier and will aim at visualizing and consolidating its content.

11.2.5 Continuous surveillance, judgement and assessment of the factory production control by an approved body

The manufacturer shall keep his metallurgical dossier updated. Prior to the periodical inspection, the approved body shall evaluate the updating of the metallurgical dossier prepared by the manufacturer relating to initial type testing and factory production control and will have requested necessary complementary information.

The periodical inspection shall be conducted after acceptance of the metallurgical dossier and will aim at visualising and consolidating its content.

12 Application for certification

The manufacturer, who intends to grant for a certification shall address a demand to OCAB-OCBS.

Upon receipt of this demand, OCAB-OCBS will transmit to the manufacturer a proposal with a set of documents including:

- The particular rules regarding the CE-marking,
- The present operating procedure,
- A copy of the certification agreement,
- The applicable tariff and fees.

The manufacturer, who wishes to start the certification procedure, sends back the duly signed and approved proposal to OCAB-OCBS. The certification process is then started.

13 Example of Certificate

An example of certificate forwarded is illustrated below.

Draft not yet approved by the Board

Attestation of Conformity (AoC)

2+



Boulevard de la Plaine Pleinlaan, 5

B 1050 BRUSSELS

1148 - CPD - 200XNN

By the Belgian Law on the application of the directive 89/106/EEC of the Council of European Communities of 21 December 1988 relating to the construction products (Construction Products Directive - CPD), it has been stated by OCAB-OCBS (Notified Body N°1148) and MET (Notified Body N°1147) that

Name of the Producer

Full address

in its factory of **FACTORY**

applies a

**Factory Production Control (FPC) according to EN 14399-1
for High-strength structural bolting assemblies for
preloading and the Further Testing of Samples taken at the factory
in accordance with a prescribed test plan.**

The approved body has performed the **Initial Inspection** of the factory and of the factory production control and performs the **Continuous Surveillance**, assessment and approval of the factory production control laid down in the harmonized standard EN 14399-1 : 200X.

This certificate attests that all provisions concerning the attestation of conformity described in Annex ZA of the standard were applied. This certificate remains valid as long as the conditions laid down in the harmonized standard or the manufacturing conditions in the factory or the FPC itself have not changed significantly.

<City, Date>

<Authorized signatures>



1148 - CPD - 200XNN

Name of the Producer in its factory of **FACTORY**

AoC 2+ List of Approved Products for **20XX**

Products	Qualities and Grades	Dimensions
Harmonised Standard under reference: hEN 14399-1:200x		
All Products, all Qualities and Grades, all Dimensions listed hereunder		
Harmonised Standard under reference: hEN 14399-2:200x		
Harmonised Standard under reference: hEN 14399-3:200x		
Harmonised Standard under reference: hEN 14399-4:200x		
Harmonised Standard under reference: hEN 14399-5:200x		
Harmonised Standard under reference: hEN 14399-6:200x		
Harmonised Standard under reference: hEN 10xxx-x:200x		
Harmonised Standard under reference: hEN 10xxx-x:200x		
Harmonised Standard under reference: hEN 10xxx-x:200x		

<City, Date>

<Authorized signatures>