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**CE Marking Technical Compliance File**  
*General Correspondence*Created by: Th. Schmidt  
Dated: 08 July 2010

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**Scope:**

This Technical File covers the complete Equipment Design, Manufacturing and Testing Documentation. It shall address all applicable Directives. The structure of the file is not regulated, however, it must be possible to collect or retrieve all information systematically and in a short period of time.

**Content**

1. General Description of the Product (What is it? What does it? How is it used?)
2. Drawing(s)
  - 2.1. Drawing List
    - 2.1.1. Design and Manufacturing Drawings
    - 2.1.2. Assembly Drawing
    - 2.1.3. Description and explanations necessary to understand said drawings and layout, as well as operation of the product
3. Bill of Material of all Parts
4. Design Calculation and/or Evaluations/Validations
5. List of Applied Standards
6. Risk Assessment for all applicable Directives
7. Official Approval Certificates (e.g. Design Approval Certificates, CE Declaration of Conformity or Certificate of Integration as related to applied Equipment)
8. Inspection and Test Reports
9. Material Traceability
  - 9.1. Materials (e.g. including heat number reference sheet, if required for strength validation)
  - 9.2. Material Manufacturer QA System Certificate (it shall include manufacturer's statement confirming material condition, if required for strength validation)
  - 9.3. MTR's (Mill Test Reports)
10. Particular Material Appraisals per applicable Material Grade (if applicable)
11. Welding
  - 11.1. Weld Map
  - 11.2. Component List  
(Note: When no welding has been performed, a statement will be in the file, documenting it.  
Note: Identify Fit-Up Welds with '\*' and add Note to page, stating that welding procedures and welder for fit-up welds do not need to be approved or certificated, if the fit-up weld will be fully removed, either by mechanical or by welding during production.)
  - 11.3. Welder Approval Log  
(Note: Shall be signed by QA as part of the final inspection)

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- 11.4. Welding Procedure Approval Record
- 11.5. Welder Welding Operator Certificates
- 12. Electrical Equipment
  - 12.1. Description
  - 12.2. Means or Operation
  - 12.3. Type of Certification
- 13. Assembly / Machine Handbook
  - 13.1. Operation Instruction (Validated by Design and Risk Assessment)
  - 13.2. Installation Instruction (Validated by Design and Risk Assessment)
  - 13.3. Maintenance Instructions (Validated by Design and Risk Assessment)
- 14. Declaration of Conformity

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**Instructions:**

- (a) All machinery must be accompanied by instructions including at least the following:
- a repeat of the information with which the machinery is marked, except the serial number together with any appropriate additional information to facilitate maintenance (e.g. addresses of the importer, repairers, etc.),
  - foreseen use of the machinery within the meaning of 1.1.2(c),
  - workstation(s) likely to be occupied by operators,
  - instructions for safe:
    - putting into service,
    - use,
    - handling, giving the mass of the machinery and its various parts where they are regularly to be transported separately,
    - assembly, dismantling,
    - adjustment,
    - maintenance (servicing and repair),
    - where necessary, training instructions,
    - where necessary, the essential characteristics of tools which may be fitted to the machinery.

Where necessary, the instructions should draw attention to ways in which the machinery should not be used.

- (b) The instructions must be drawn up in one of the Community languages by the manufacturer or his authorized representative established in the Community. On being put into service, all machinery must be accompanied by a translation of the instructions in the language or languages of the country in which the machinery is to be used and by the instructions in the original language. This must be done either by the manufacturer or his authorized representative established in the Community or by the person introducing the machinery into the language area in question. By way of derogation from this requirement, the maintenance instructions for use by specialized personnel employed by the manufacturer or his authorized representative established in the Community may be drawn up in only one of the Community languages understood by those personnel.
- (c) The instructions must contain the drawings and diagrams necessary for putting into service, maintenance, inspection, checking of correct operation and, where appropriate, repair of the machinery and all useful instructions in particular with regard to safety.
- (d) Any literature describing the machinery must not contradict the instructions as regards safety aspects. The technical documentation describing the machinery must give information regarding the airborne noise emissions referred to in (f) and, in the case of hand-held and/or hand-guided machinery, information regarding vibration.
- (e) Where necessary, the instructions must give the requirements relating to installation and assembly for reducing noise or vibration (e.g. use of dampers, type and mass of foundation block, etc.).

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- (f) The instructions must give the following information concerning airborne noise emissions by the machinery, either the actual value or a value established on the basis of measurements made on identical machinery:
- equivalent continuous A-weighted sound pressure level at workstations, where this exceeds 70 dB(A); where this level does not exceed 70 dB(A), this fact must be indicated,
  - peak C-weighted instantaneous sound pressure value at workstations, where this exceeds 63 Pa (130 dB in relation to 20  $\mu$ Pa),
  - sound power level emitted by the machinery where the equivalent continuous A-weighted sound pressure level at workstations exceeds 85 dB(A). In the case of very large machinery, instead of the sound power level, the equivalent continuous sound pressure levels at specified positions around the machinery may be indicated

Where the harmonized standards are not applied, sound levels must be measured using the most appropriate method for the machinery.

The manufacturer must indicate the operating conditions of the machinery during measurement and what methods have been used for the measurement

Where the workstation(s) are undefined or cannot be defined, sound pressure levels must be measured at a distance of 1 meter from the surface of the machinery and at a height of 1,60 meters from the floor or access platform. The position and value of the maximum sound pressure must be indicated.

- (g) If the manufacturer foresees that the machinery will be used in a potentially explosive atmosphere, the instructions must give all the necessary information.
- (h) In the case of machinery which may also be intended for use by non-professional operators, the wording and layout of the instructions for use, whilst respecting the other essential requirements mentioned above, must take into account the level of general education and acumen that can reasonably be expected from such operators.

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## Marking

All machinery must be marked legibly and indelibly with the following minimum particulars:

- name and address of the manufacturer,
- the CE marking (see Annex III),
- designation of series or type,
- serial number, if any,
- the year of construction.

Furthermore, where the manufacturer constructs machinery intended for use in a potentially explosive atmosphere, this must be indicated on the machinery.

Machinery must also bear full information relevant to its type and essential to its safe use (e.g. maximum speed of certain rotating parts, maximum diameter of tools to be fitted, mass, etc.).

Where a machine part must be handled during use with lifting equipment, its mass must be indicated legibly, indelibly and unambiguously.

The interchangeable equipment referred to in the third indent of Article 1(2)(a), must bear the same information.

## Warning of residual risks

Where risks remain despite all the measures adopted or in the case of potential risks which are not evident (e.g. electrical cabinets, radioactive sources, bleeding of a hydraulic circuit, hazard in an unseen area, etc.), the manufacturer must provide warnings.

Such warnings should preferably use readily understandable pictograms and/or be drawn up in one of the languages of the country in which the machinery is to be used, accompanied, on request, by the languages understood by the operators.