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Guidance to conformity marking of lifting products for which there is no harmonized standard.

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LIFTING EQUIPMENT ENGINEERS ASSOCIATION
3 Osprey Court, Kingfisher Way
Hinchingbrooke Business Park
Huntingdon PE29 6FN
United Kingdom
Tel: + 44 (0) 1480 432801 Fax: + 44 (0) 1480 436314
E-mail: mail@leea.co.uk Website: www.leeaint.com

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1.0 Introduction

New lifting equipment placed on the market in Europe and the United Kingdom requires a declaration of conformity which must state the standards or specifications used in the development of the product.

LEEA strongly supports full compliance with the relevant product standards, particularly the harmonized or approved standards which carry a presumption of conformity with the legal requirements for the supply of new lifting equipment. However, it is recognised that in some circumstances there is a requirement for a product that must deviate from the requirements of the general purpose item covered by the product standard.

In many cases the reason for the deviation may be something minor, in which case the standard will often provide the majority of the specification and LEEA 056 has guidance in this case. However, in some cases the deviation will be considerable.

In the case whereupon the reason for deviation is minor, for example a webbing sling designed in accordance with EN 1492 with the exception of the colour, the manufacturer need only address those requirements with which their product does not comply. However it is important that any reference to the standard in the manufacturer's literature or documentation is clear and not ambiguous or misleading. If a manufacturer is considering this approach, then they should refer to LEEA 056 for best practice guidance on the method.

If the deviation from the standard is considerable, for example in the case of stainless-steel chain slings, then the manufacturer must not base the assessment of their product on a similar product standard, i.e. EN 818. In fact doing so would be considered inadequate in terms of the requirements of the Machinery Directive 2006/42/EC, Supply of Machinery (Safety) Regulations 2008 (SOMSR) and section 6 of the Health and Safety at Work etc. Act 1974 (HSWA).

This guidance document has been developed by LEEA as a means of ensuring that the manufacturer of equipment not covered by a harmonized standard is compliant with the supply legislation.

2.0 Standards and Legislation

The primary legislation is the Supply of Machinery (Safety) Regulations 2008 for the United Kingdom and the European Machinery Directive 2006/42/EC for the EEA.

In terms of standards the most relevant for all products within scope of the supply legislation is EN ISO 12100. This standard specifies basic terminology, principles and a methodology for achieving safety in the design of machinery. It specifies principles of risk assessment and risk reduction to help designers in achieving this objective. These principles are based on knowledge and experience of the design, use, incidents, accidents and risks associated with machinery. Procedures are described for identifying hazards and estimating and evaluating risks during relevant phases of the machine life cycle, and for the elimination of hazards or provision of sufficient risk reduction. Guidance is given on documentation and verification of the risk assessment and risk reduction process. This standard is generally used for the preparation of type B and Type C standards. Many product safety standards are type C.

3.0 The Conformity Assessment of Lifting Equipment.

The legislation enforces the conformity assessment procedure that must be carried out by the manufacturer before lifting equipment can be placed on the market or put into service. This conformity assessment is mandatory, however, for certain categories of lifting equipment, the manufacturer can choose between several alternative procedures. The following sections describe each of the different approaches which may be used, but for clarity, figure 1 summarises the different options that are available.

3.1 Equipment for Goods Lifting Only.

Note the following procedure is not applicable to vehicle service lifts.

The procedure to be followed is the procedure for assessment of conformity with internal checks on the manufacture, see figure 1. This procedure does not require the intervention of a notified body. However, the manufacturer is free to seek independent advice or assistance if he needs to carry out the conformity

assessment of the lifting equipment. He may carry out the checks, inspections and tests and inspections needed to assess the conformity of the lifting equipment himself or entrust them to any competent body of his choice. The relevant technical reports must be included in the technical file.

It must be noted that there are no Notified (approved UK) Bodies for categories of lifting equipment other than those used as a vehicle service lifts or those used for people carrying where there is a hazard of a fall from

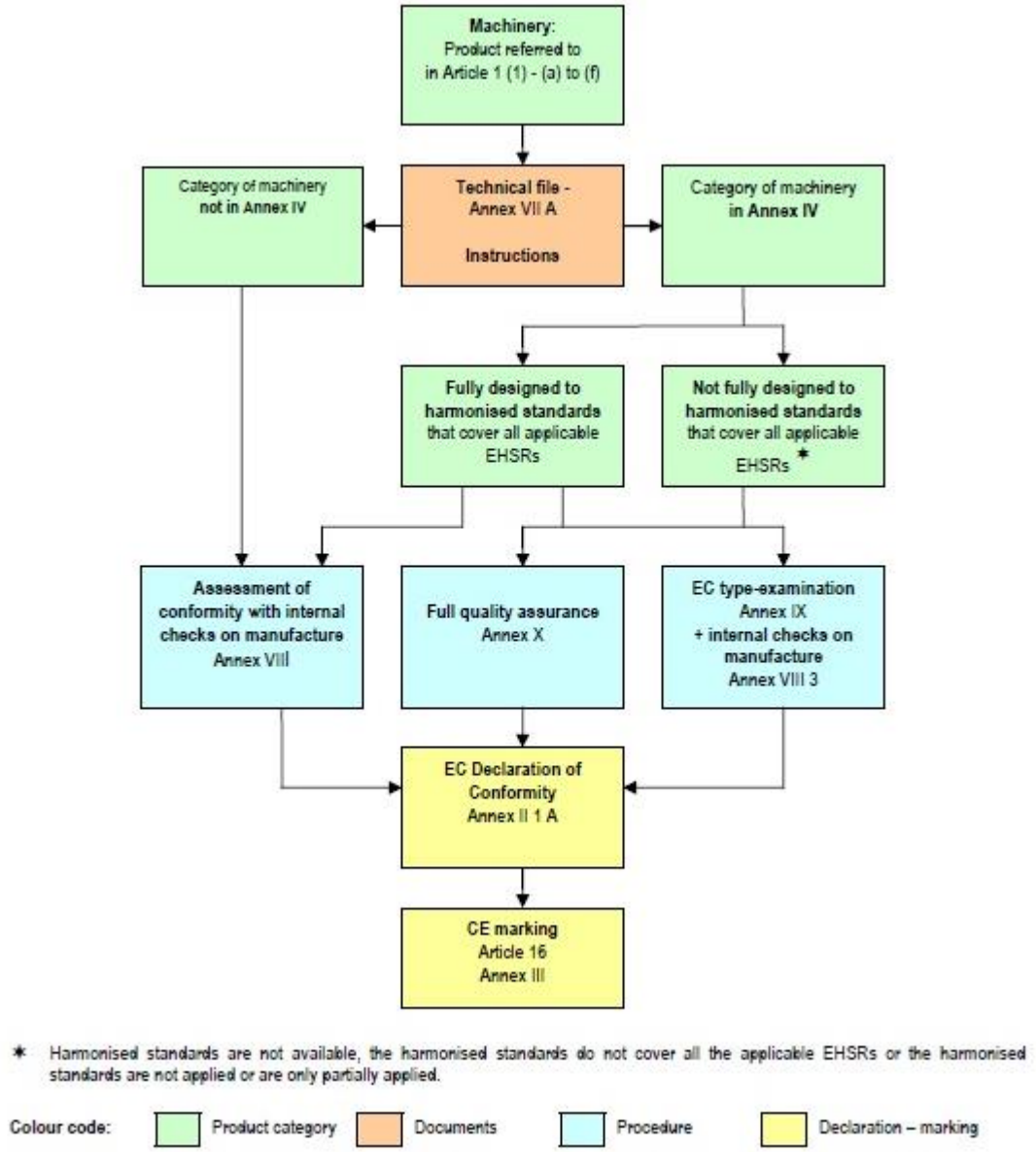

Figure 1: Flow chart summarising the procedures for placing on the market of machinery. The annexes referred to are those within directive 2006/42/EC. Source Guide to application of the Machinery Directive 2006/42/EC 2nd Ed. June 2010; European Commission.

height above three meters. Therefore if using a Notified body for any other items of lifting equipment then the body is not acting as a Notified Body and must not use the identification number assigned to it by the Commission on any documents relating to such activity.

In simple terms the requirement for the assessment of conformity is to draw up a technical file. The technical file must identify the Essential Health and Safety Requirements (EHSRs) applicable to the lifting equipment and then describe how they have been fulfilled. This would normally be in the form of the manufacturer's product standard, and the simplest way for ensuring that the product meets the EHSRs, would be to design it in accordance with a current harmonised/approved standard. However,

in the absence of such a standard then the requirement is for the manufacturer to produce their own, refer to section 4.0 for guidance on how to do this.

To satisfy the requirement for internal checks the manufacturer must take the measures necessary to ensure that the manufacturing process ensures compliance of the manufactured lifting equipment with the technical file and the applicable EHSRs. The specific measures will vary depending on the product, but typically they may include quality control, inspection, measurement, testing, NDT, etc.

3.2 Vehicle Service Lifts and People Carrying Lifting Equipment.
In terms of lifting equipment the only items covered by annex IV of the SOMSR or Machinery Directive are vehicle service lifts and any equipment which is designed to lift people involving a hazard of falling from a height greater than 3 metres.

In this case the procedure for the assessment of conformity will depend on whether or not the equipment is designed in accordance with a harmonized standard or not. The following sections deal with each case separately.

3.2.1 Vehicle service lifts and people carrying lifting equipment designed to a harmonized standard that covers all of the applicable EHSRs.
In this instance there are three choices for the conformity assessment procedure that may be applied by the manufacturer of this type of equipment, which are:

1. The procedure for assessment of conformity with internal checks on the manufacture of the lifting equipment, refer to section 3.1.

2. A EC type-examination procedure, plus the above internal checks on the manufacture of the lifting equipment. An EC type-examination is the procedure whereby a Notified Body is chosen to examine each model or type of equipment. The Notified Body checks the documentation, including the technical file that is drawn up by the manufacturer, and carries out necessary tests and inspections on samples of the lifting equipment to ensure that the model or type is designed and constructed in conformity with the applicable EHSRs. The conformity of the lifting equipment subsequently produced according to the model examined by the Notified Body is then assessed by the manufacturer by means of internal checks, refer to section 3.1.

3. A full quality assurance procedure, which requires the manufacturer to have a full quality assurance system covering the design, manufacture, final inspection and testing of the lifting equipment. The system must be assessed and approved by a Notified Body to ensure that it is adequate to ensure the design and manufacture of the lifting equipment that complies with the EHSRs that are applicable. The Notified Body must also monitor the correct application of the full quality assurance system, but the manufacturer is not obliged to have each type of lifting equipment examined.

3.2.2 Vehicle service lifts and people carrying lifting equipment not fully covered by a harmonized standard that covers all of the applicable EHSRs.
This only applies to the manufacturer when:

- Harmonised standards covering the type of lifting equipment concerned are not available;
- The harmonised standards applied by the manufacturer do not cover all of the EHSRs applicable to the equipment concerned;
- The manufacturer of the equipment concerned has not applied or has only partially applied the relevant harmonised standard.

In such cases, the procedure for assessment of conformity with internal checks on the manufacture of lifting equipment cannot be used and, consequently, only points 2 or 3 of section 3.2.1 above can be applied.

4.0 Risk Assessment and Risk Reduction
In the absence of a harmonised standard then the designer must do his own conformity assessment against the EHSRs of the supply legislation. To assist the designer in this LEEA recommends that the procedures and guidance within EN ISO 12100 are applied. If this is done then this standard may be listed on the EC Declaration of Conformity drawn up for the equipment.

In summary, EN ISO 12100 is a strategy for risk assessment and risk reduction and to implement each of these the designer is required to take the following actions in the order given:

- Determine the limits of the lifting equipment, which include the intended use and any foreseeable misuse thereof;
- Identify the hazards and associated hazardous situations;
- Estimate the risk for each identified hazard or hazardous situation;
- Evaluate the risk and take decisions about the need for risk reduction;
- Eliminate the hazard or reduce the risk associated by means of protective measures.

The first four points listed above are all associated with risk assessment, with the last point being applicable to risk reduction.

The primary objective when considering the above is the greatest practicable risk reduction, taking into account the following key factors:

- The safety of the machine during all the phases of its life cycle;
- The ability of the machine to perform its function;
- The usability of the machine;
- The manufacturing, operational and dismantling costs of the machine.

The risk assessment and the resulting risk reduction must be fully documented. Typically the risk assessment will result in a list of potential hazards associated with the equipment and a list of the potential consequences of the hazard. For example a common hazard would be a mechanical hazard, such as sharp edges, and the consequence of this hazard could be cutting or severing.

Once a list of potential hazards and their consequences has been devised the designer would then need to devise means of reducing the occurrence and/or severity of the identified consequences. In order to adequately reduce the risks the following hierarchy to design must be adhered to;

- Eliminate or reduce the risk as far as possible through inherent safe design and construction;
- Take the necessary protective measures in relation to risks that cannot be eliminated;
- Inform the user of residual risks due to any short comings of the protective measures adopted.

The approach to be taken must be specified and documented and cross referenced to the associated hazard. For example:

- A mechanical hazard, such as sharp edges, resulting in cuts while handling the equipment.

In this instance the method to be adopted would be to eliminate the risk, by specifying in the document that all sharp edges and burs must be removed following the manufacturing process. This information would be in a sub clause of the document and the sub clause number will be added against the hazard and consequence in the list to it can be easily cross referenced.

In order for the machine to function as designed it may not be possible to design out an identified hazard. For example, a portal crane travelling on tracks installed on the ground has the potential to crush personal in the danger zone. To avoid this the second approach must be adopted and protective measures should be put in place to reduce the probability of the risk occurring. This could be done by fitting an acoustic system and flashing lights to warn personal that the equipment is in motion. Although this will reduce the risk, it does not eliminate it. Therefore the last resort should be implemented and an instruction to warn users should be provided, perhaps in the form of a training requirement.

The final document should then be added to the technical file for the equipment in the form of a specification to which all items covered by the technical file are manufactured.

4.1 Checks on Manufacture

The checks on manufacture are the measures necessary to ensure that the manufacturing process is in compliance with the risk reduction requirements, and therefore the EHSRs, as documented in the

technical file. The specific measures will vary depending on the product, but typically they may include quality control, inspection, measurement, testing, NDT, etc.

To evidence that the requirements of the specification have been followed in full, then the manufacturer must also include in the technical file any data accrued during the process. This data would typically be in the form of test reports, material certificates, NDT results, etc.