Supplying Machinery to Europe and Compliance with European Requirements.

A short guide for suppliers of machinery into Europe.

Overview.

Free movement of goods is a basic principle within the European Union (EU). To explain the 'New Approach', the Guide to the implementation of directives based on the New Approach and the Global Approach has been developed. Very simply, Directives become laws, and must be complied with, supported by voluntary Harmonised EN Standards that if followed, have a presumption of conformity to the Essential Safety Requirements in the Directives. Applying the CE mark demonstrates compliance.

The aim of this document is to help manufacturers of Machinery to be able to supply safe, CE marked machinery into the European Economic Area. More information on the Single European Market can be found on the Europa website.

Contents:

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1. Main Directives relevant to Machinery

Directives are produced by committees within the EU, approved by the European Commission and brought into the law of each Member State in a given timescale. A number of Directives may apply to a machine, or assembly of machines. It is the manufacturers' responsibility to determine which Directives apply, and to meet all requirements of each Directive that applies. Application of the CE marking shows that the manufacturer has met these obligations. The Guide to the application of the Machinery Directive 2006/42/EC gives additional guidance on which Directives apply in paragraphs 90 to 92.

2006/42/EC Machinery Directive

The original Directive 89/392/EEC was introduced in January 1993, with a two year transition period to allow manufacturers to comply. Machinery supplied from January 1995 had to carry CE marking and be safe. This Directive was modified a number of times and re-issued as 98/37/EC.

It was then updated and rewritten with some changes and additions in 2006, issued as 2006/42/EC and came into force on 29th December 2009. All machinery supplied into the EEA from this date should comply with the 2006/42/EC Directive. Most machinery can be self-declared, and does not need additional certification; however, there must be a person in Europe responsible for making the Technical File available to Health and Safety Authorities as required.

2014/30/EU Electromagnetic Compatibility (EMC)

The original EMC Directive 89/336/EEC from 1992 was updated and re-written as 2004/108/EC. Following a transition period, it came into force on 20th July 2009. This Directive was replaced with **2014/30/EU** from 20th April 2016. The EMC Directive limits electromagnetic emissions of equipment in order to ensure that such equipment does not disturb radio, telecommunication and other equipment. The Directive governs the immunity of such equipment to interference and seeks to ensure that this equipment is not disturbed by radio emissions when used as intended. Manufacturers should be able to demonstrate compliance with the Directive within the Technical File, by providing test results or an EMC Technical File.

2014/68/EU Pressure Equipment (PED)

PED applies from 30th May 2002. The original 97/23/EC Directive was replaced from 19th July 2016. It concerns items such as vessels, heat exchangers, steam generators, pressurised storage containers, boilers, industrial piping, pressure accessories and safety devices. Equipment in Module A is self-declaration, if not in Module A, a Notified Body must be involved. There must be a person within the EU, responsible for holding documentation.

2014/29/EU Simple Pressure Vessels

'Simple pressure vessel' means any welded vessel subjected to an internal gauge pressure greater than 0,5 bar which is intended to contain air or nitrogen and which is not intended to be fired. CE marking should be applied to pressure vessels. This Directive replaced 2009/105/EC from 20th April 2016.

2014/34/EU Equipment and protective systems for potentially explosive atmosphere (ATEX)

The original 94/9/EC ATEX Directive applied from 1st July 2003 and addresses equipment and protective systems intended for use in potentially explosive atmospheres. It covers a large range of products, including equipment used on fixed offshore platforms, in petrochemical plants, mines, flour mills and other areas where a potentially explosive atmosphere may be present. A potentially explosive atmosphere is defined as 'air mixtures of gases, vapours, mists or dusts, which can ignite under certain operating conditions'. Often a Notified Body will need to be involved. The Directive 94/9/EC was replaced from 20th April 2016.

2000/14/EC Noise Emission by Equipment for Use Outdoors

This Directive applies to 57 types of outdoor equipment. Manufacturers of equipment of this type must follow the requirements. Those listed in Article 12 are subject to noise limits and require Notified Body assistance. Those listed in Article 13 are self-declaration. The majority of these types are also in the scope of the Machinery Directive. It is a requirement to send a copy of the Declaration to each Member State and to the Commission for each type of unit supplied. This information is collated into a database within the Outdoor Noise pages on the Europa website.

92/58/EEC Safety Signs

The format for warning signs used on machinery within Europe is laid down in the Safety Signs Directive. For Machinery there are three types of signs, Warnings which are triangular with a yellow background and a black border; Mandatory, which are white symbols on a round blue background; and Prohibition, which are round, with a red border and red bar across, with black symbols on a white background. This Directive does not require application of the CE marking. EN ISO 7010 details the symbols that are acceptable for use on equipment in the EU.

2006/95/EC Low Voltage Directive

Where machinery has an electricity supply, it must be designed, constructed and equipped in such a way that all hazards of an electrical nature are or can be prevented. The safety objectives set out in the Low Voltage Directive (LVD), apply to machinery. However, obligations concerning conformity assessment, placing on the market and/or putting into service of machinery regarding electrical hazards are governed solely by the Machinery Directive 2006/42/EC. Generally, the LVD should not be identified on a Declaration of Conformity of Machinery.

In case of sub-supply of the machinery's switch-gear and control panel by another manufacturer, the corresponding EC Declaration of Conformity should be requested for the Technical File. 2006/42/EC was replaced with **2014/35/EU** on 20th April 2016.

In all cases, even if a Notified or Certification Body is involved, the manufacturer must issue the Declaration, to demonstrate compliance with all applicable Essential Safety Requirements.

'One-off' machines or complex assemblies of machines being supplied into Europe must comply with all relevant Directives on the date they are put into service. For series of the same machine being supplied into Europe, the manufacturer must ensure changes to the Directives are met.

Each Directive has its own page on the Europa website, www.europa.eu/, where the Directive can be downloaded freely. Many have guidance documents that can also be downloaded. For

the full list of New Approach Directives and their applicable EN standards, please see http://www.newapproach.org/Directives/DirectiveList.asp. If a New Approach Directive applies to the equipment, it needs to be addressed.

2. Harmonised European Standards for Machinery Safety

Harmonised Standards are either EN - European Standard or EN ISO - EN identical with an ISO Standard. The European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (CENELEC) provide the voluntary EN Standards, developed by committees involving business and other stakeholders.

The aim is to produce high-quality standards for products and services that incorporate safety, quality, environmental, interoperability and accessibility requirements. They actively support international standardisation, and co-operate closely with the International Organisation for Standardisation (ISO) and the International Electrotechnical Commission (IEC), in order to pursue the goal of 'one standard, one test, accepted everywhere'.

Standards can be purchased from a number of sources, they are not free to download, unlike Directives. EU states have their own Standards organisations, standards can be purchased from any, it is worth shopping around as prices vary greatly. The application of Harmonised Standards is voluntary, except where a Directive refers directly to certain EN (e.g. Outdoor Noise Directive regarding noise test standards).

Harmonised standards get their status of providing Presumption of Conformity after their issue, by their listing in the Official Journal of the EU under the relevant Directive. There could be a delay of listing in or withdrawal from the Official Journal or a limitation of their Presumption of Conformity as an outcome of a possible safeguard procedure by the Commission; therefore the manufacturer should always check the listing of the standard to be applied.

The list of harmonised standards can be found on the websites of each Directive, for Machinery it is http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/machinery/index_en.htm. The website New Approach Standardisation in the Internal Market lists all of the New Approach Directives and their Harmonised Standards.

2.1 Structure of Harmonised EN standards

There are three types of harmonised EN Standard, Types A, B and C.

A Type standards (basic safety standards) giving basic concepts, principles for design and general aspects that can be applied to machinery;

B Type standards (generic/group safety standards) dealing with one safety aspect or one type of safeguard that can be used across a wide range of machinery. A distinction is made between:

• B1 standards on particular safety aspects (e.g. noise, safety distances, temperatures);

• B2 standards on safeguards (e.g. access, control systems, guards, interlocking devices);

C Type standards (specific machinery safety standards) giving detailed safety requirements for a particular type of machine or group of machines.

A and B Type standards can be used as aids when designing machinery. They prevent repetition of general specifications and ensure technical consistency of C type standards for particular safety aspects and safety devices. When a C type standard deviates from one or more provisions dealt with by a B type standard, the C type standard takes precedence.

The basis for Machinery Safety is provided by the A type standard **EN ISO 12100: 2010** Safety of machinery - General principles for design - Risk assessment and risk reduction. This is the only A type standard, and was created by amalgamating the previous EN 12100 Parts 1 and 2, with EN 14121-1 on Risk Assessment. EN ISO 12100 has been adopted by most industrial countries. All machinery manufacturers should have EN ISO 12100.

B Type standards

There are a number of B Type standards. Listed below are some that are useful in many different types of machine. This is not a full list, but contains many of the common standards required.

EN ISO 4413:2010 Hydraulic fluid power - General rules and safety requirements for systems and their components

EN ISO 4414:2010 Pneumatic fluid power - General rules and safety requirements for systems and their components

EN ISO 13732-1:2008 Ergonomics of the thermal environment - Methods for the assessment of human responses to contact with surfaces - Part 1: Hot surfaces (Part 3 for Cold surfaces).

EN ISO 13849-1:2008/AC 2009 Safety of machinery - Safety-related parts of control systems - Part 1: General principles for design

EN ISO 13849-2:2012 Safety of machinery. Safety-related parts of control systems. Validation

EN ISO 13850:2008 Safety of machinery - Emergency stop - Principles for design

EN ISO 13855:2010 Safety of machinery - Positioning of safeguards with respect to the approach speeds of parts of the human body

EN ISO 13857:2008 Safety of machinery - Safety distances to prevent hazard zones being reached by upper and lower limbs

EN ISO 14119: 2013 Safety of machinery - Interlocking devices associated with guards - Principles for design and selection

EN ISO 14120:2015 Safety of machinery. Guards. General requirements for the design and construction of fixed and movable guards

EN ISO 14122-1:2001 A1:2010 Safety of machinery - Permanent means of access to machinery - Part 1: Choice of fixed means of access between two levels. Parts 2-4 provide detailed information

EN 60204-1:2006/AC:2010 Safety of machinery - Electrical equipment of machines - Part 1: General requirements

C Type standards

C Type standards are for specific types of machine. If there is a C Type standard for the machinery being built, compliance to the standard can save time and effort.

All C Type standards have a similar structure:-

The **Foreword** indicates whether the standard was prepared under a mandate given by the European Commission to become a Harmonised Standard.

The **Scope** defines the machinery with its limitations and, if applicable, indicates if a certain hazard is not dealt with.

Normative References detail other standards and documents that may be applicable.

The **List of Hazards** contains the risk analyses performed by standards makers who have included all significant hazards known to them. The designer must, establish whether the machine to be built involves any further hazards and must take corresponding safety measures.

The section on **Safety Requirements and/or Protective Measures** contains specifications both in the form of results and design solutions. It may define a requirement for testing or providing calculations to demonstrate safety. There is usually a section on verification of safety measures.

The section on **Information for Use** includes requirements concerning marking and data which should be included in the instructions. In this section, standards should refer to residual risks which it has not been possible to eliminate by inherent safety and safeguarding. The information determined by the designer as being useful or necessary for minimising these residual risks, e.g. wearing personal protective equipment etc., should also be given to the user or operator.

3. How to Comply

Since the Machinery Directive is a New Approach Directive, manufacturers have the following options, all of which require full compliance with the Essential Safety Requirements – ESRs. Most machinery is self-declaration, no outside body is needed, although sometimes it is easier to use consulting organisations to assist. In some cases, Notified Bodies are required, especially with relation to equipment listed in Annex IV of the Machinery Directive, or equipment that the Pressure Equipment Directive or ATEX Directive applies to.

Option 1: Compliance with the Machinery Directive (Not using harmonised EN Standards)

The manufacturer compiles a Technical File[1] which includes a report addressing all of the relevant Essential Safety Requirements, explaining how the manufacturer has met each of the relevant requirements. Risk assessments demonstrating compliance to the ESR's are essential.

Option 2: Compliance with A & B Type harmonised EN Standards

Where EN Standards refer to ESR's in Annex ZA[2], voluntary compliance to these standards provides presumption of conformity to the corresponding ESR's of the EC Directive(s). Referring to these standards makes it easier for the manufacturer to prove compliance with the ESRs.

When a manufacturer chooses not to apply harmonised standards or to apply only parts of a harmonised standard, he must include in the technical file the risk assessment undertaken and the steps taken to comply with the essential health and safety requirements. Presumption of Conformity is only given within the limits of the scope of the standard and the ESRs dealt with.

Option 3: Compliance with a C Type harmonised EN Standard

Following a C Type Standard provides presumption of conformity to the ESR's listed in Annex ZA. If there are further hazards or ESRs related to the machinery not dealt with in the C type standard, compliance has to be proved by using B type standards or risk assessment.

The manufacturer or his authorised representative must carry out a Risk Assessment to decide which ESRs apply to the machinery, and take necessary protective measures. In case of queries by a market surveillance authority the manufacturer has to prove compliance with the ESRs.

3.1 Practical Compliance

To carry out CE marking of machinery, the relevant Articles and Annexes of the Directive should first be read and understood. First, check whether the equipment being supplied comes under the definition of machinery. If it does, then to prove compliance, a Technical File needs to be developed which should contain all of the reports and test results that demonstrate that the machine meets the Essential Safety Requirements.

Article 1 of the Directive lists the scope of what is included and excluded from the Directive. This is the list of included equipment.

(a) machinery;
(b) interchangeable equipment;
(c) safety components;
(d) lifting accessories;
(e) chains, ropes and webbing;
(f) removable mechanical transmission devices;
(g) partly completed machinery.

Article 2 has definitions of all of these items.

The Machinery Directive 2006/42/EC consists of a series of recitals, 29 articles and 12 annexes, *(those relevant for the manufacturer are in **bold letters**)*:

[1] See Section 4 of this document for details of what should be in a Technical File.

[2] The majority of harmonised EN Standards list the ESR's applicable in Annex ZA, however, if there are additional Annexes, derived usually from an international Standard, the annex ZA may be ZB, ZC etc.

Articles 1 to 7 – Scope, placing on the market and freedom of movement;

Articles 8 to 11, 15 and 18 to 23 – Measures by the member states and the Commission;

Articles 12 to 14 – Procedures for assessing the conformity;

Articles 16 and 17 – CE marking;

Article 24 – Amendment of Lift Directive 95/16/EC;

Articles 25 to 29 - Final provisions

The annexes contain detailed requirements augmenting the provisions of the main body of the Directive and have the same legal character - they are not merely informative.

Annex I is of most significance to manufacturers since it contains the mandatory Essential Health and Safety Requirements – ESRs for machinery as far as they apply.

Annex II is divided into two parts:

Part A specifies the contents of the **EC Declaration of Conformity** of the machinery, which the manufacturer must provide for every machine placed on the European market ready for use.

Part B specifies the contents of the **Declaration of Incorporation** of partly completed machinery, which is intended for incorporation into machinery or assembly with other machinery to constitute an assembly of machinery functioning as an integral whole.

Annex III describes the symbol used for **CE marking**.

Annex IV lists particularly hazardous machinery for which a special certification procedure involving a Notified Body may be required, if the machinery is not manufactured in accordance with harmonised C type standards covering all relevant essential health and safety requirements.

Annex V covers an indicative list of safety components. This is not a definitive list due to rapidly changing technology.

Annex VI explains the Assembly Instructions for partly completed machinery.

Annex VII describes the procedure for compiling the Technical File for machinery or the relevant technical documentation for partly completed machinery. The Technical File must be compiled in an official Community language. Part A is for machinery, Part B for partly completed machinery.

Annex VIII describes the procedure by the manufacturer for Assessment of Conformity with internal checks on the manufacture of machinery.

Annex IX establishes the procedure for obtaining an EC Type-examination certificate for Annex IV machinery from a Notified Body.

Annex X describes the procedure for conformity assessment of Annex IV-machinery, manufactured using a Full Quality Assurance system.

Annex XI specifies the minimum criteria that a notified body is to fulfil and Annex XII contains a table comparing the structure of the current Machinery Directive 2006/42/EC to that of the previous Directive 98/37/EC.

Compliance of machinery with the Directive is achieved by fulfilment of the relevant **Essential Health and Safety Requirements** (ESR's)[3]. The ESR's in **Annex I** only apply when the corresponding hazard exists for the machinery in question if used under the conditions foreseen by the manufacturer, or in foreseeable abnormal situations (reasonably foreseeable misuse).

Before consideration of the ESRs the General Principles of Annex I shall be noted.

3.2 Risk Assessment

It is necessary to carry out a Risk Assessment in order to determine which ESRs apply, preferably by using a harmonised C type standard (if it exists) and/or EN ISO 12100:2010.

Then either each clause of the relevant C Type standard, or each of the ESR's needs to be addressed, the ESR's are mandatory, and have to be complied with as far as possible. The ESR's are in six sections. Every machine needs to be reviewed to Section 1, then each section if

[3] Generally a report showing how each ESR has been addressed or complied with.

it applies. If there is a C Type EN standard, there is the presumption of conformity to the ESR's listed, should it be followed.

As the ESR's are reviewed, it is best to document in what ways the machine complies; this is done by risk assessment[4]. If the risk assessment determines that the machine is hazardous, then it should be re-designed or modified in such a way as to make it safe. Some ESR's will not apply.

The first ESR has definitions that apply; it is notable that the definition of an operator includes the person or persons installing, operating, adjusting, maintaining, cleaning, repairing or moving machinery, not just the person using the machine. It is useful to document at this stage what the intended use for the machine is, also any foreseeable misuse that there may be. This can be reviewed at a later date, but is a good point to start with.

Section 1.1 covers generic safety, ensuring that the products that the machine uses or generates do not lead to a hazard and that the equipment can be handled safely; that the ergonomic issues have been addressed and to ensure that the operating positions do not lead to strain or stress.

Section 1.2 covers control systems, and brings in safety related control system standards such as EN 13849 or EN 62061. Generally this will lead to the generation of a report showing the assessment of Performance Level or Safety Integration Level for each safety function, and the validation of the architecture and components used to meet the assessment. It continues with the need to ensure that controls are clearly identified and logically positioned, and that the machine can be started and stopped without putting people in danger. It covers the need for Emergency Stops, whether for individual machines or how they apply to the whole assembly. It also addresses how the machine works in the event of power fluctuation or failure.

Section 1.3 is about mechanical hazards, stability, risks due to break up, ejected objects, sharp edges and angles, variations in operating conditions and how moving parts are protected.

Section 1.4 is about guarding and protection devices, defining different types of guards.

Section 1.5 is for other hazards, starting with electricity supply. The Low Voltage Directive objectives should be addressed as should static electricity. At this point EN 60204-1 should be used. Other sources of energy, such as hydraulic, pneumatic or steam for example, should be considered at this time. Errors of fitting need to be addressed, preferably designing out any areas where incorrect connections can be made, including pneumatic, hydraulic and electrical connections. Extreme temperatures and fire should be considered. Explosion protection brings in the requirements of the ATEX Directive. Noise and vibration are covered here, and the radiation requirements bring in not only ionising radiation, but also the EMC Directive, and laser radiation. Access needs to be reviewed, to ensure there are no risks of slips, trips and falls, and that all areas of the equipment can be accessed for operation and maintenance.

Section 1.6 is about maintenance and requires that thought be given as to how the machinery can be maintained safely. Isolation of all energy sources needs to be considered. Consideration needs to be given on how to change components, the instructions require this information. Operator intervention should be brought to a minimum, and cleaning must be considered.

Section 1.7 is about information that must be provided, bringing in the Safety Signs Directive, also the information that must be on the manufacturers' plate and in the Instruction manual. Information and warnings on the machinery should be provided in the form of understandable symbols or pictograms. Any written or verbal information and warnings must be expressed in an official Community language or languages of the Member State in which the machinery is placed on the market and/or put into service, and may be accompanied, on request, by versions in any other official Community language or languages understood by the operators. Maintenance instructions for specialised personnel mandated by the manufacturer may be written in only one of the Community languages which the specialised personnel understand. (By agreement).

[4] Risk assessment is defined in EN 12100:2010, which has many examples of hazards, and how to ensure that risk reduction is achieved, to ensure that the machinery is safe when it is put into service.

The instructions cover the 'life' of the machinery, from its commissioning to disposal, and not only take into account the intended use of the machinery but also any reasonably foreseeable misuse.

C Type standards often add requirements for instructions, as do the following sections.

Foodstuffs machinery, machinery for cosmetics or pharmaceutical products, hand-held, and/or hand-guided machinery, portable fixing and other impact machinery[5], machinery for working wood and material with similar physical characteristics, must meet all of the essential health and safety requirements described in Section Two;

Machinery presenting hazards due to its mobility must meet all the essential health and safety requirements described in Section Three;

Machinery presenting hazards due to lifting operations must meet all the relevant essential health and safety requirements described in Section Four; This includes lifting accessories.

Machinery intended for underground[6] work must meet all the essential health and safety requirements described in Section Five;

Machinery presenting hazards due to the lifting of persons[7] must meet all the relevant essential health and safety requirements described in Section Six;

3.3 Protective Measures

Where compliance is not immediately achieved, protective measures are required. The measures taken to eliminate or reduce any risk throughout the foreseeable lifetime of the machinery must apply the following principles, in the order given below (see EN ISO 12100):

Step 1: Inherently safe design measures eliminate hazards or reduce the associated risks by a suitable choice of design features of the machine itself and/or interaction between the exposed persons and the machine. This stage is the only one at which hazards can be eliminated, thus avoiding the need for additional protective measures such as safeguarding or complementary protective measures.

Step 2: Safeguarding and/or complementary protective measures - Taking into account the intended use and the reasonably foreseeable misuse, appropriately selected safeguarding and complementary protective measures can be used to reduce risk when it is not practicable to eliminate a hazard, or reduce its associated risk sufficiently, using inherently safe design measures.

Step 3: Information for use - Where risks remain despite inherently safe design measures, safeguarding and the adoption of complementary protective measures, the residual risks shall be identified in the information for use. The information for use shall include, but not be limited to, operating procedures for the use of the machinery consistent with the expected ability of personnel who use the machinery or other persons who can be exposed to the hazards associated with the machinery;

3.4 Involvement of a Notified Body

For machinery listed in Annex IV and not manufactured in accordance with harmonised C type standards covering all relevant ESRs or only partly manufactured in accordance with such standards, the manufacturer shall apply one of the following procedures:-

Full quality assurance according to Annex X or

EC type-examination according to Annex IX, plus the internal checks on the manufacture of machinery provided for in Annex VIII, point 3.

[5] Many woodworking machines and impact machines are listed in Annex IV.

[6] Locomotives and brake vans for use underground, and hydraulic powered roof supports are also in Annex IV.

[7] Devices for the lifting of persons or of persons and goods involving a hazard of falling from a vertical height of more than three metres are listed in Annex IV.

Notified Bodies can only issue 'EC-type examination certificates' for Annex IV machinery - the manufacturer or authorised representative is responsible for issuing Declarations of Conformity.

Member States of the European Economic Area (EEA) and other countries, where there are 'Mutual Recognition Agreements ' or 'Agreements for Conformity Assessment and Acceptance of Industrial Products' have designated Notified Bodies to carry out the conformity assessment according to the Directive.

Notified Bodies can be found on the NANDO web site. Lists include the identification number of each Notified Body and the tasks for which it has been notified, and are regularly updated.

The notifying state's authority can decide if the Notified Body is allowed to subcontract for inspections, tests or assessment, e.g. in China, but the manufacturer remains responsible for placing his product on the European market.

4. Documentation

4.1 Technical File /Documentation

The Technical File or Documentation in relation to Annex VII must be compiled in one or more Community languages. This file shall include documentation on the risk assessment, the ESRs which apply and the description of the implemented protective measures.

If the machinery or components of it are also subject of other Directives, the corresponding EC-type examination certificates, test reports etc., EC Declarations of Conformity or Incorporation (in case of supply by another manufacturer) have to be held in the Technical File.

Drawings, calculations, a copy of the Instructions, a list of the Standards used and for series manufacture, the internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions of this Directive must also be in the Technical File.

The file must be made available to the competent authorities of the Member States for at least 10 years following the date of manufacture of an individual machine or, in the case of series machines, of the last unit produced.

The file does not have to be located in the territory of the EEA, nor does it have to be permanently available in material form. However, it must be made available within a period of time commensurate with its complexity by the person designated in the Declaration.

Failure to present the Technical File in response to a duly reasoned request by the authorities may constitute sufficient grounds for doubting the conformity of the machinery with the ESRs.

4.2 Declarations

The machinery must be accompanied by a Declaration in a Community language, and a translation thereof in the official language(s) of the Member State in which it is placed on the market and/or put into service (as the instructions). There are two different Declarations:

EC Declaration of Conformity for machines or complex assemblies of machines ready for use should contain, according to Annex II-1A:-

• the business name and full address of the manufacturer and where appropriate, his authorised representative;

• name and address of the person – who must be established in the EEA - authorised to compile the Technical File in accordance with Annex VII-A;

• a description of the machinery, including function, model, type and serial number.

• a sentence declaring that the machinery fulfils all the relevant provisions of this Directive and where appropriate, a similar sentence declaring the conformity with other Directives and/or relevant provisions with which the machinery complies[8].

• if a Notified Body has been involved, the details and number of the Notified Body.

• where appropriate, reference to the harmonised standards used.

• place and date of the declaration as well as the identity and signature of the person empowered to draw up the declaration on behalf of the manufacturer or his authorised representative.

Declaration of Incorporation of partly completed machinery should contain according to Annex II-1B:-

• the business name and full address of the manufacturer and where appropriate, his authorised representative;

• name and address of the person – who must be established in the EEA - authorised to compile the Technical documentation in accordance with Annex VII-B;

• a description of the machinery, including function, model, type and serial number.

• a sentence declaring which Essential Requirements of the Directive are applied and fulfilled and that the relevant Technical Documentation is compiled, and where appropriate, a sentence declaring the conformity of the partly completed machinery with other relevant Directives;

• an undertaking to transmit, in response to a reasoned request by the national authorities, relevant information on the partly completed machinery;

• a statement that the partly completed machinery must not be put into service until the final machinery into which it is to be incorporated has been declared in conformity with the provisions of this Directive;

• place and date of the declaration as well as the identity and signature of the person empowered to draw up the declaration on behalf of the manufacturer or his authorised representative.

4.3 CE marking

Before placing machinery - except partly completed machinery - on the market and/or putting it into service, the manufacturer or his authorised representative shall affix the CE marking.

Where machinery is also the subject of other Directives, and providing for the affixing of the CE marking, the marking shall indicate that the machinery also conforms to the provisions of those other Directives. In this case the CE marking might be amended by the identification number of the Notified Body (Directives ATEX, Lift, Pressure Equipment) or indicating the guaranteed sound power level for products covered by the Outdoor Noise Directive.

Where machinery hazards referred to in Annex I are wholly or partly covered more specifically by other Community Directives (e.g. explosion hazards by the ATEX Directive), the Machinery Directive shall not apply, or shall cease to apply, to that machinery in respect of such hazards from the date of implementation of those other Directives.

The affixing on machinery of markings, signs and inscriptions likely to mislead third parties as to the meaning or form of the CE marking, is prohibited. Any other marking may be affixed to the machinery provided that the visibility, legibility and meaning of the CE marking is not impaired.

With regard to voluntary Quality marks, they are market /customer driven, mainly consumer products - tested by Competent Bodies on Safety; Environmental Impact, Usability, etc., usually to an EN Standard. There is no legal obligation for such marks, however, consumers in some EU Member States have a higher confidence in products with such quality marks. The manufacturer is still responsible for issuing the Declaration and applying the CE marking.

[8] There is only one Declaration required for machinery. However, the formal requirements of any other applicable Directives have to be integrated.

Annex 1 Other Directives broadly related to machinery

2001/95/EC General Product Safety for Consumer Products

85/374/EEC Product Liability for Consumer Products

Directives on certain Hazards or Aspects

2012/19/EU Waste from Electrical and Electronic Equipment

2011/65/EU Hazardous Substances in Electronic Equipment

Type-Approval of Motor Vehicles and their Trailers

Type-Approval of Agricultural or Forestry tractors, their Trailers and Interchangeable Towed Machinery

Indirect related Directives on Safety and Health at Work - for information only

2003/10/EC Risks arising from physical agents – Noise

2002/44/EC Risks arising from physical agents – Vibration

2013/35/EU - Electromagnetic fields

2014/33/EU on Lifts deals with lifting machinery, which is excluded from the Machinery Directive. However, for all relevant hazards not dealt with in its Annex I, the essential requirements of the Machinery Directive apply. The Lift Directive defines various phases of conformity assessment procedures, using the modules of the modular approach. Compliance with Harmonised Standards gives presumption of conformity to the ESRs. As from 29th December 2009 the Directive was amended by the Machinery Directive 2006/42/EC providing more precise delineation between the Lift and Machinery Directives. Directive 95/16/EC was replaced by **2014/33/EU** on 20th April 2016.

Annex 2 Other Resources

LinkedIn – There are a number of Groups that address CE Marking, including the Machinery Directive 2006/42/EC group.

COMPLIANCE Risk Software allows organisations to address EHSR's, carry out risk assessments and create Technical Files and Declarations to Machinery and Low Voltage Directives.

Machinebuilding.net is a website with a lot of information for machinery manufacturers.

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Safe Machine Ltd