

How I Learned to Stop Worrying and Love the Machinery Directive

Experiences working with the
EU Machinery Directive
(2006/42/EC)

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What is this presentation about?

A brief discussion of:

- * Does the Machinery Directive (MD) apply to you?
(MD = 63 pages, MD Guide = 406 pages)
- * Why does it apply?
(maybe you make machinery ... or maybe not)
- * If it applies, what do you do about it?
(how to start your evaluation)
- * Can you learn to love the MD too?
(considering you came to this presentation ...)

Why should I care about the Machinery Directive?

1. I want to ship products to Europe.
2. My products are covered by the Machinery Directive.
3. I want to comply with the EU law.

If all three items apply to you and your products, then you do care about the Machinery Directive.

Let's assume #1 and #3 and take a look at #2.

Scope of the MD

Article 1

Scope

1. This Directive applies to the following products:
 - (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.

Scope of the MD (continued)

Let's see if we can ignore some of these categories:

Article 2

Definitions

The following definitions shall apply:

(b) 'interchangeable equipment' means a device which, after the putting into service of machinery or of a tractor, is assembled with that machinery or tractor by the operator himself in order to change its function or attribute a new function, in so far as this equipment is not a tool;

Scope of the MD (continued)

Is that clear, now? How about this one:

- (c) 'safety component' means a component:
- which serves to fulfil a safety function,
 - which is independently placed on the market,
 - the failure and/or malfunction of which endangers the safety of persons, and
 - which is not necessary in order for the machinery to function, or for which normal components may be substituted in order for the machinery to function.

If you make & sell light curtains for safety, you make machines, even if they have no moving parts.

Scope of the MD (continued)

To save time I will limit the discussion to:

- (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.

Scope of the MD (continued)

But wait! That's not all. We have started to look at what is machinery, but we need to look at what is not machinery.

2. The following are excluded from the scope of this Directive:

(a) safety components intended to be used as spare parts to replace identical components and supplied by the manufacturer of the original machinery;

(b) specific equipment for use in fairgrounds and/or amusement parks;

(c) machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in an emission of radioactivity;

(d) weapons, including firearms;

(e) the following means of transport ... with the exclusion of machinery mounted on these means of transport;

(f) seagoing vessels and mobile offshore units and machinery installed on board such vessels and/or units;

(g) machinery specially designed and constructed for military or police purposes;

(h) machinery specially designed and constructed for research purposes for temporary use in laboratories;

(i) mine winding gear;

(j) machinery intended to move performers during artistic performances;

(k) electrical and electronic products falling within the following areas, insofar as they are covered by Council Directive 73/23/EEC [Low Voltage Directive] ...: household appliances intended for domestic use, audio and video equipment, information technology equipment, ordinary office machinery, low-voltage switchgear and control gear, electric motors;

(l) the following types of high-voltage electrical equipment: switch gear and control gear, transformers.

Scope of the MD (continued)

Three areas could use a bit more consideration:

(a) safety components intended to be used as spare parts to replace identical components and supplied by the manufacturer of the original machinery;

- your spare parts are not considered separate machines

(h) machinery specially designed and constructed for research purposes for temporary use in laboratories;

- this lets research scientists build an apparatus ... but not you

(k) electrical and electronic products falling within the following areas, insofar as they are covered by Council Directive 73/23/EEC [Low Voltage Directive]: household appliances intended for domestic use, audio and video equipment, information technology equipment, ordinary office machinery, low-voltage switchgear and control gear, electric motors;

- if your equipment is fully in one of these categories (such as ITE), you're out of here! (But ITE may be part of a machine.)

Scope of the MD (continued)

Article 3 of the MD also states that the Machinery Directive does not apply to machines for the risks covered more specifically by other EU Directives.

When other Directives cover all the risks associated with the machines, the machines are entirely excluded from the scope of the Machinery Directive.

Examples are the Toy Directive and the Medical Devices Directive, but not the Low Voltage Directive.

When the specific Directives only cover some of the risks associated with the machines, the machines are in the scope of the Machinery Directive for the remaining risks.

An example is the ATEX Directive, which applies - for the explosion hazard - to machinery intended for use in potentially explosive atmospheres. The MD applies for other hazards.

Scope of the MD (continued)

Getting back to our remaining two categories:

(a) 'machinery' means:

— an assembly, fitted with or intended to be fitted with a [a] drive system other than directly applied human or animal effort, consisting of [b] linked parts or components, at least [c] one of which moves, and which are [d] joined together for a specific application,

— an assembly referred to in the first indent, missing only the components to connect it on site or to sources of energy and motion, [no power cord or air hose – it's still a machine]

— an assembly referred to in the first and second indents, ready to be installed and able to function as it stands only if mounted on a means of transport, or installed in a building or a structure, [must attach to a vehicle or building to operate – such as a gantry crane]

— [a] assemblies of machinery referred to in the first, second and third indents or partly completed machinery referred to in point (g) which, in order to achieve the same end, are [b] arranged and controlled so that they function as an integral whole,

— an assembly of linked parts or components, at least one of which moves and which are joined together, intended for lifting loads and whose only power source is directly applied human effort; [an exception to indent 1 that specifically excludes “directly applied human or animal effort”]

For each indent 1 and 4 all the points highlighted must be true for a device to be considered a machine.

Scope of the MD (continued)

For example, a machine is (indent 1) -

“an assembly, fitted with or intended to be fitted with a

[a] drive system other than directly applied human or animal effort, consisting of

[b] linked parts or components, at least

[c] one of which moves, and which are

[d] joined together for a specific application”

[a] electric motor
[b] assembled
[c] blades move
[d] application is to provide hot air - Fan is part of the specific application



Heater with fan
>> a machine

[a] electric motor
[b] assembled
[c] blades move
[d] application is to provide electricity - Fan enables the p.s. to perform its specific application



Power supply with fan
>> not a machine

Scope of the MD (continued)

Question – When is a machine not a machine?

Answer #1 – When it's a “partly completed machine”.

(g) ‘partly completed machinery’ means an assembly which is [a] almost machinery but which [b] cannot in itself perform a specific application. A drive system is partly completed machinery. Partly completed machinery is [c] only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery to which this Directive applies;

This distinction is similar to the UL category of “Recognized Component” because partly completed machines have some lack that must be remedied in the final product.

This distinction also is important because the required documentation and marking is different for machines and partly completed machines.

ALL the itemized points must be true for partly completed machines.

Scope of the MD (continued)

So the MD covers machines, assemblies of machines and partly completed machines (as well as the items we ignored earlier), and it does not cover ITE (and the other items we mentioned earlier). Now you should know if it applies to your products.

All clear so far?

Let's take a look at some machines ... or are they? While you watch the [Benchbot video](#) consider which instruments are compliant machines, which are partly completed machines, and why? And is the "assembly of machines" shown in the video a compliant machine?

(http://www.chem.agilent.com/en-US/Products/Instruments/automation/benchbot/Pages/benchbot_video.aspx)

Scope of the MD (concluded)

A few loose ends to tie up (from the MD Guide):

(1) For machinery to be supplied without a drive system:

- risk assessment must include the drive system
- instructions must include the specs and installation of the drive system
- assessment must cover the specs of the drive system and the instructions;
- CE-marking and DofC must cover the specs and instructions for the drive system

Otherwise, machinery without a fully specified drive system must be considered partly completed machinery.

(2) Machinery that can in itself perform its specific application but which only lacks the necessary protective means or safety components is not to be considered as partly completed machinery.

(3) The MD is applicable to machinery driven by manual effort which is not applied directly but stored, for example in springs or in pneumatic tanks, so that the machinery can function after the manual effort has ceased.

“Manufacturer” per the MD

Now that we’ve figured out what is covered by the MD, we’re ready to go, right? Almost!

One more definition to consider: Who is the Manufacturer?

(i) ‘manufacturer’ means any natural or legal person who designs and/or manufactures machinery or partly completed machinery covered by this Directive and is responsible for the conformity of the machinery or the partly completed machinery with this Directive with a view to its being placed on the market, under his own name or trademark or for his own use. In the absence of a manufacturer as defined above, any natural or legal person who places on the market or puts into service machinery or partly completed machinery covered by this Directive shall be considered a manufacturer

That means someone must be responsible, but it need not be the actual builder of the product (machine) or system (assembly of machines). It could be the distributor, installer or end user.

“Manufacturer” per the MD (concluded)

Question – When is a machine not a machine?

Answer #2 – When it’s a “machine” without safety guards.

Perhaps a customer wants to buy your machine (or system), but does not want to buy the protective guards or light curtain because he already has an enclosure for the machine.

A machine without required guards ...

- is not compliant and cannot have a DofC and CE marking
- is not a partly completed machine and cannot have a DofI

... but it can be included as part of a complete machine by the Manufacturer of the end product, who may be your customer.

Then your customer must comply with all the MD requirements!

So what do I do to comply with the MD?

We've figured out (a) your product is a machine (or partly completed machine), and (b) you are the Manufacturer. Now what?

- If the units concerned are placed on the market as complete machinery that could also operate independently, they must bear the CE-marking and be accompanied by an EC Declaration of Conformity.
- If they are placed on the market as partly completed machinery, they shall not bear the CE-marking but must be accompanied by a Declaration of Incorporation and assembly instructions.

Let's first look at what goes into the technical files that back up these Declarations.

Documentation

From MD Annex VII - Technical file for machinery

The technical file must demonstrate that the machinery complies with the requirements of this Directive. It must cover the design, manufacture and operation of the machinery to the extent necessary for this assessment.

1. The technical file shall comprise the following:

(a) a construction file including:

- a general description of the machinery,
- the overall drawing of the machinery and drawings of the control circuits, as well as the pertinent descriptions and explanations necessary for understanding the operation of the machinery,
- full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check the conformity of the machinery with the essential health and safety requirements,

[i.e. - what does the “complies-with-the-EHSRs” machine look like?]

Documentation (continued)

— the documentation on **risk assessment** demonstrating the procedure followed, including:

- (i) a list of the essential health and safety requirements which apply to the machinery,
- (ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, when appropriate, the indication of the residual risks associated with the machinery,

[hazard identification, risk assessment, risk reduction, residual risks]

— the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards,

— any technical report giving the results of the tests carried out either by the manufacturer or by a body chosen by the manufacturer or his authorised representative,

[standards & tests used – do you have “presumption of conformity”?]

Documentation (continued)

- a copy of the instructions for the machinery, **[everything affecting safety]**

- where appropriate, the declaration of incorporation for included partly completed machinery and the relevant assembly instructions for such machinery,

- where appropriate, copies of the EC declaration of conformity of machinery or other products incorporated into the machinery,

- [especially for “assemblies of machines” that include several devices]**

- a copy of the EC declaration of conformity;

(b) ... internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions of this Directive. ... relevant reports and results shall be included in the technical file.

[essentially, quality and supplier control, production testing, etc.]

But note that “the technical file does not have to include detailed plans or any other specific information as regards the subassemblies used for the manufacture of the machinery unless a knowledge of them is essential for verification of conformity with the essential health and safety requirements.”

Documentation (continued)

From MD Annex VII - Technical documentation for partly completed machinery

The documentation must show which requirements of this Directive are applied and fulfilled. It must cover the design, manufacture and operation of the partly completed machinery to the extent necessary for the assessment of conformity with the essential health and safety requirements applied.

It shall comprise the following:

(a) a construction file including:

— the overall drawing of the partly completed machinery and drawings of the control circuits,

[operating instructions may be needed, if applicable]

— full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check the conformity of the partly completed machinery with the applied essential health and safety requirements,

[for partly completed machinery, the “applied” EHSRs will not include all of them – the DoI will specify which ones the product meets]

Documentation (continued)

— the risk assessment documentation showing the procedure followed, including:

- (i) a list of the essential health and safety requirements applied and fulfilled, **[This list shows which EHSRs still must be fulfilled in the end product.]**
 - (ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, where appropriate, the indication of the residual risks,
 - (iii) the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards,
 - (iv) any technical report giving the results of the tests carried out either by the manufacturer or by a body chosen by the manufacturer or his authorised representative,
 - (v) a copy of the assembly instructions for the partly completed machinery; **[The assembly instructions must accompany the partly completed machinery, along with the DoI, both appropriately translated.]**
- (b) for series manufacture, the internal measures ... **[Quality control again]**

Documentation (concluded)

So what documentation do you need to gather before writing a Declaration and sending it with your product?

1. Risk assessment
2. Product description
3. Construction evaluation and test reports (using applicable standards, preferably those listed under the MD)
4. Declarations for the devices that are part of your product
5. Instructions, including installation
6. Quality control

Let's look briefly at item 1, then conclude this presentation with what goes into the Declarations of Conformity and Incorporation.

But first ... what are the **Essential Health and Safety Requirements** and where do they come from?

MD – EHSRs in Annex I

Where: *ANNEX I* - Essential health and safety requirements relating to the design and construction of machinery

The Key: If you can show your product satisfies all the EHSRs in Annex I that are applicable, then you can put on the CE marking.

Q – Do you need to use only standards under the MD?

A – No.

Q – Are you sure?

A – Yes. Those standards give “presumption of conformity” to the MD (when used appropriately), but each EHSR can be shown to be complied with in other ways (although you may be expected to meet a higher standard of proof).

MD – EHSRs in Annex I (continued)

What: Essential health and safety requirements stated in Annex I vary from general

“The materials used to construct machinery or products used or created during its use must not endanger persons' safety or health.”)

- to more specific

“Internal parts requiring frequent inspection and adjustment, and maintenance areas must be provided with appropriate lighting.”).

You have to decide which EHSRs apply to your product and how to show your product meets them. The easiest way to do it is to use standards, whether under the MD or not. If a standard doesn't cover all the EHSRs, use other standards to complete your evaluation.

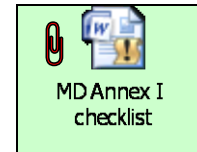
MD – EHSRs in Annex I (continued)

For example – if you want to use IEC 61010-1 (Safety requirements for electrical equipment for measurement, control, and laboratory use) to evaluate your equipment under ...

LVD – gives presumption of conformity – you're done!

MD – does not give presumption of conformity – evaluate under 61010 and complete a checklist for Annex I that shows which EHSRs are met with your 61010 evaluation and which EHSRs are met by using other standards, tests or considerations.

Annex I checklist >



MD – EHSRs in Annex I (concluded)

So what's the first thing stated at the beginning of Annex I?

GENERAL PRINCIPLES

1. The manufacturer of machinery or his authorised representative must ensure that a risk assessment is carried out in order to determine the health and safety requirements which apply to the machinery. The machinery must then be designed and constructed taking into account the results of the risk assessment.

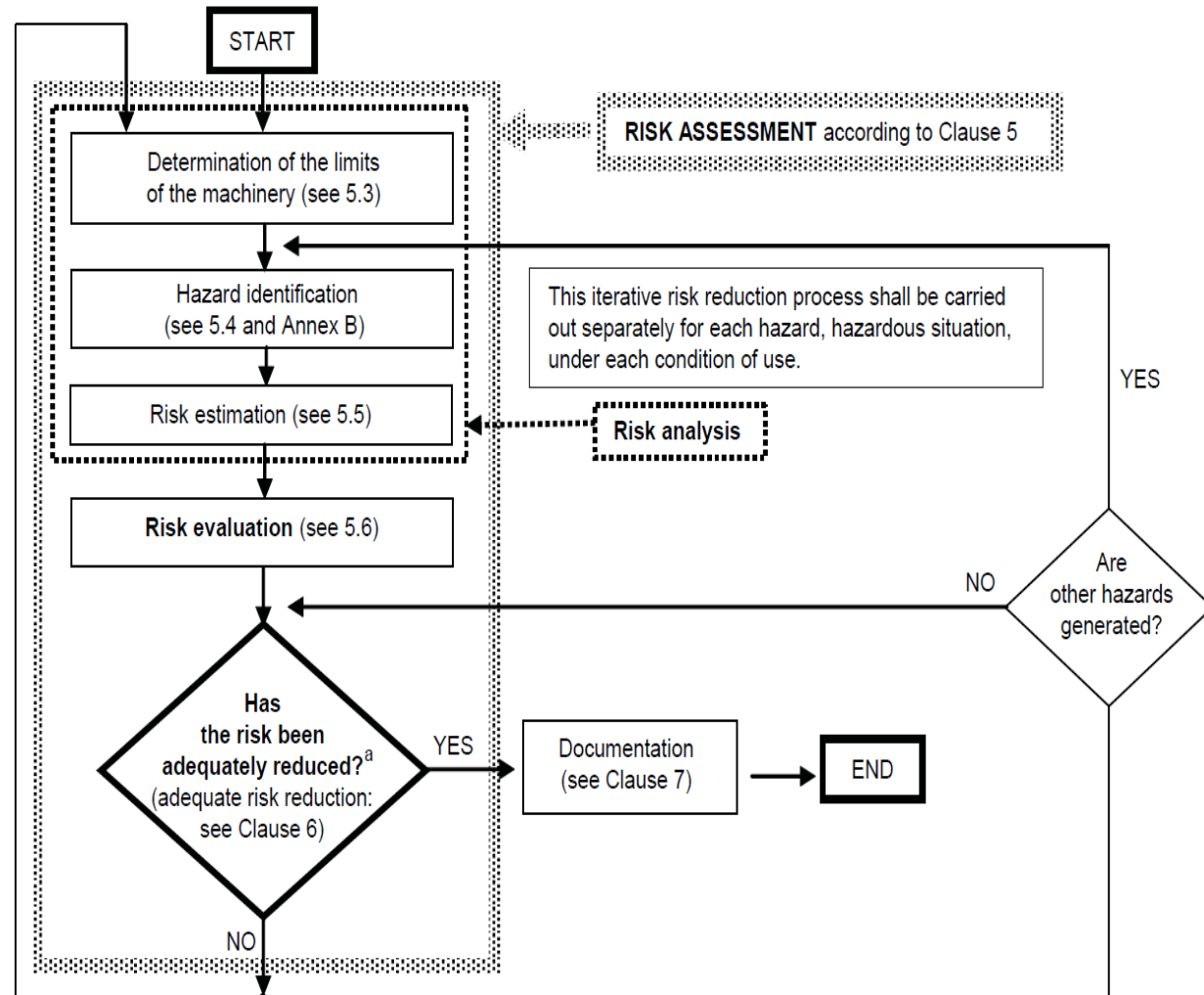
Let's take a quick look at Risk Assessment.

Risk Assessment

There are several standards dealing with risk assessment and reduction.

Recommended:
ISO 12100:2010
Safety of machinery
— General principles
for design — Risk
assessment and risk
reduction

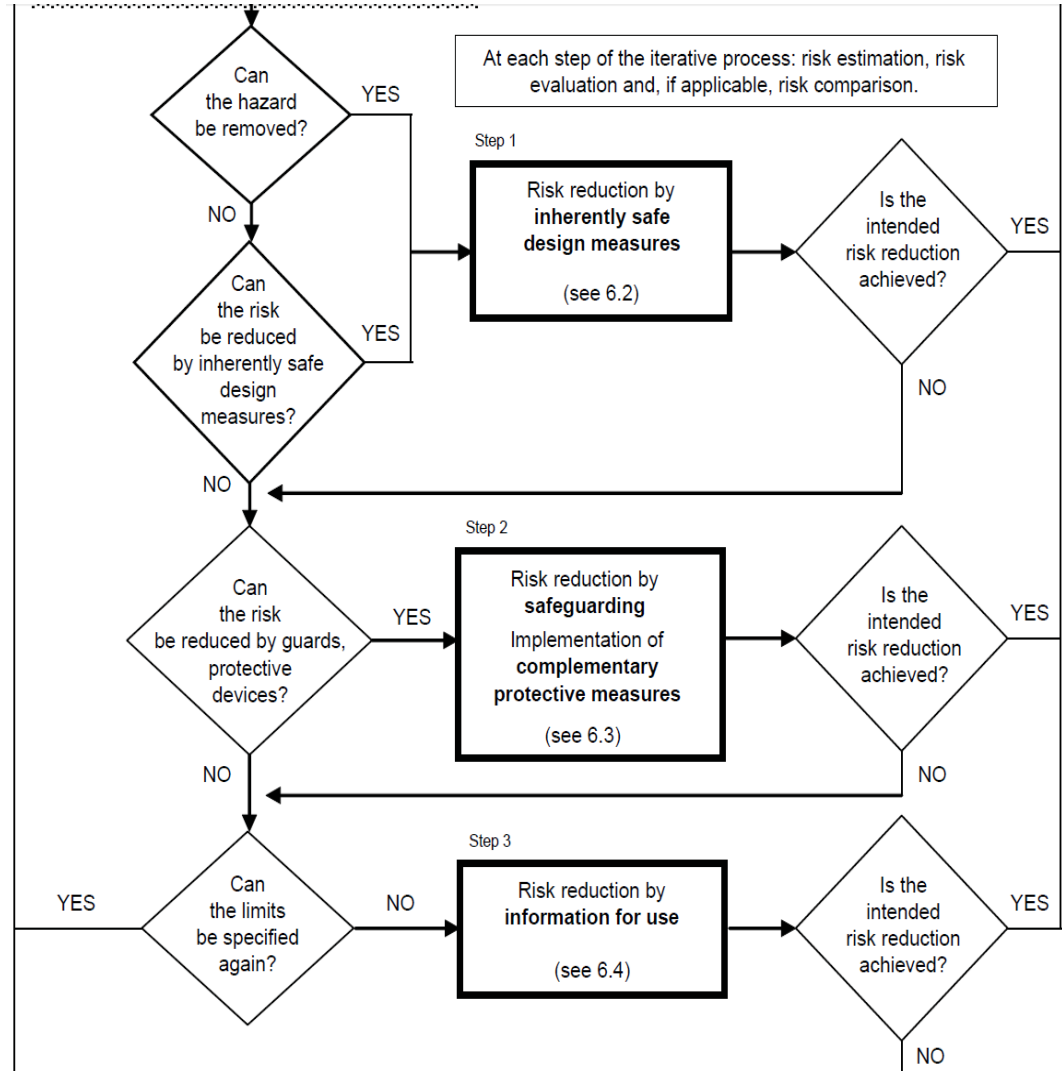
The assessment process is repeated during product development as the design changes.



Risk Assessment (continued)

There is a **REQUIRED** hierarchy of design for risk reduction:

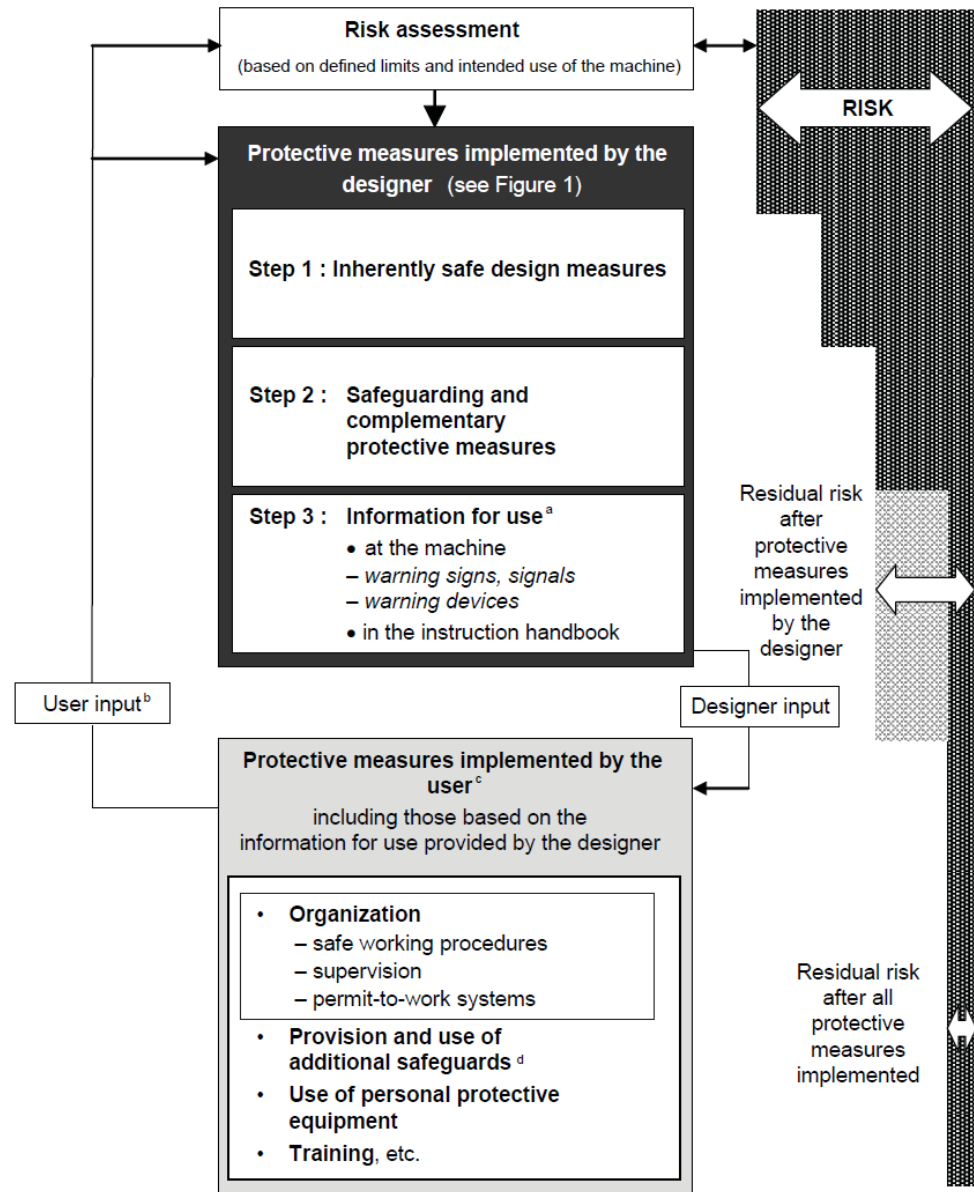
- inherently safe design
- safeguards for hazards
- instructions to users



Risk Assessment (continued)

Another way to look at risk assessment and risk reduction.

Note that the amount of “residual risk” acceptable must be decided by the Manufacturer, based on the type of product, expected users, “state of the art”, and so on.



Risk Assessment (concluded)

Here is one example of an FMEA (Failure Mode and Effects Analysis) table in a format that is useful for completing and documenting the Risk Assessment. >



Note that

“Severity x Occurance x Detection = Risk Priority Number”.

The actual RPN number limit for acceptable residual risk depends on the assigned scales for each quantity and must be decided by the Manufacturer.

There are many variations on this theme, but I recommend using the least complex approach that will meet your needs.

Finally, a look a Declarations of Conformity and Incorporation.

Declarations

Annex II - A. EC DECLARATION OF CONFORMITY OF THE MACHINERY

This declaration and translations thereof must be drawn up under the same conditions as the instructions and must be typewritten or handwritten in capital letters. [translated into the applicable EU language and marked “Translation” and accompanied by an “Original”, if no verified Original is available in that language.]

This declaration relates exclusively to the machinery in the state in which it was placed on the market, and excludes components which are added and/or operations carried out subsequently by the final user.

The EC declaration of conformity must contain the following particulars:

1. business name and full address of the manufacturer and, where appropriate, his authorised representative;
2. name and address of the person authorised to compile the technical file, who must be established in the Community;
3. description and identification of the machinery, including generic denomination, function, model, type, serial number and commercial name;

Declarations (continued)

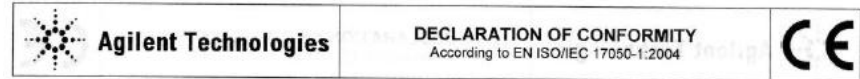
- A. EC DECLARATION OF CONFORMITY OF THE MACHINERY (cont.)
4. a sentence expressly declaring that the machinery fulfils all the relevant provisions of this Directive and where appropriate, a similar sentence declaring the conformity with other Directives and/or relevant provisions with which the machinery complies.; [but NOT the LVD if compliant with the MD]
 5. [only for Annex IV categories of machinery – e.g. woodworking equipment];
 6. [only for Annex IV categories of machinery];
 7. where appropriate, a reference to the harmonised standards used, as referred to in Article 7(2); [when using “presumption of conformity”]
 8. where appropriate, the reference to other technical standards and specifications used;
 9. the place and date of the declaration;
 10. the identity and signature of the person empowered to draw up the declaration on behalf of the manufacturer or his authorised representative.

Declarations (continued)

This Declaration is for a custom system (assembly of machines), so specific details of the equipment and the layout for the system are included as part of the DoFC.

The other required elements also are included.

Note that no mention is made of the Low Voltage Directive, although the system does comply with it as well as with the MD and the EMCD.



Manufacturer's Name: Agilent Technologies, Inc.
Automation Solutions Business
5301 Stevens Creek Boulevard
Santa Clara, California 95051
USA

Manufacturer's Address:

Declares under sole responsibility that the product as originally delivered

Product Name & Function: BenchCel Laboratory Robot Workstation System
Model & Part Numbers: Model G5400A
Product Options: As described in Attachments A and B
Serial Number USS2011360010

complies with the essential requirements of the following applicable European Directives, and carries the CE marking accordingly:

EMC Directive 2004/108/EC
Machinery Directive 2006/42/EC

and conforms with the following product standards:

EMC: IEC 61326-1:2005 / EN 61326-1:2006
Safety: IEC 61010-1:2001 / EN 61010-1:2001
IEC 61010-2-081:2001 / EN 61010-2-081:2002

Supplementary Information:

The products were tested in a typical configuration with Agilent Technologies test systems. See Attachments A and B for details of system content and configuration.

This DoC applies to above-listed products placed on the EU market after:

01 November, 2011

Date

Santa Clara, CA

Location

A handwritten signature in black ink, appearing to read "Roy Kiesling".

Roy Kiesling

ASB Quality Manager

Contact established in the Community authorized to compile the technical file or the relevant technical documents:

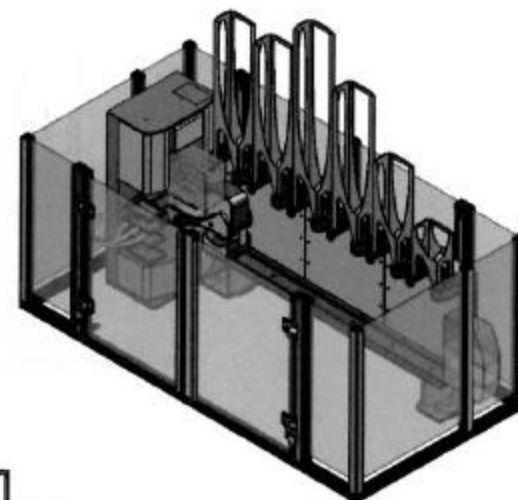
Agilent Technologies Deutschland GmbH
Herrenbergerstrasse 130
71034 Boblingen
Germany

Declarations (continued)

Attachment A:

List of components for BenchCel Laboratory Robot Workstation System (G5400A), SN USS2011360010

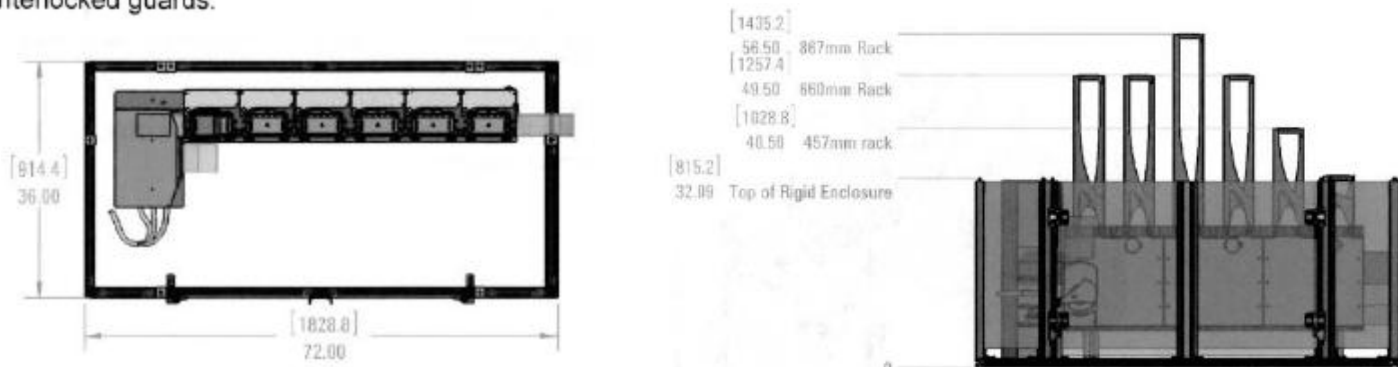
Material	Material Description	Qty	Serial number
02318-201	Vertical Pipetting Station, Stand-alone	1	SGS11VPS12401
06118-001	Pump Module, Universal Voltage	1	SGS10LHAA3801
06118-001	Pump Module, Universal Voltage	1	SGS11LHAA2904
06147-202	96 Channel Fixed Head, 200ul, Stainless	1	31.0011
08330-400	Vworks Simulation License	1	45-01725
08330-402	Vworks Benchtop License	1	45-01784
10648-101	Desktop Computer	1	USS2011420007
18692-206	BenchCel 6R	1	SGS11BCL33501
G5486-60027	BenchBot Disable Hub	1	USS2011430030
	Interlocked Rigid Enclosure	1	Configured per drawing



Attachment B:

Configuration layout drawing for BenchCel Laboratory Robot Workstation System (G5400A), SN USS2011360010

Note that the desktop computer, pump modules and disable hub may be configured outside the interlocked guards.



Declarations (continued)

Annex II - B. DECLARATION OF INCORPORATION OF PARTLY COMPLETED MACHINERY

This declaration and translations thereof must be drawn up under the same conditions as the instructions, and must be typewritten or else handwritten in capital letters. [same as DofC]

The declaration of incorporation must contain the following particulars:

1. business name and full address of the manufacturer of the partly completed machinery and, where appropriate, his authorised representative;
2. name and address of the person authorised to compile the relevant technical documentation, who must be established in the Community;
3. description and identification of the partly completed machinery including generic denomination, function, model, type, serial number and commercial name;

Declarations (continued)

B. DECLARATION OF INCORPORATION OF PARTLY COMPLETED MACHINERY

4. a sentence declaring which essential requirements of this Directive are applied and fulfilled and that the relevant technical documentation is compiled in accordance with part B of Annex VII, and, where appropriate, a sentence declaring the conformity of the partly completed machinery with other relevant Directives.;
5. an undertaking to transmit, in response to a reasoned request by the national authorities, relevant information on the partly completed machinery. This shall include the method of transmission and shall be without prejudice to the intellectual property rights of the manufacturer of the partly completed machinery;
6. 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, where appropriate;
7. the place and date of the declaration;
8. the identity and signature of the person empowered to draw up the declaration on behalf of the manufacturer or his authorised representative.

Declarations (concluded)

 Agilent Technologies	DECLARATION OF INCORPORATION According to Directive 2006/42/EC, Annex II, part B
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This template includes the required elements and leaves blanks for itemizing specific characteristics (applicable Essential Health and Safety Requirements) with which the partly completed machine does not comply.

Not being able to perform a specific application - one of the requirements to be a complete machine – also may be included.

No CE marking is described and no mention is made of the LVD, although the product may comply with it as well as with the EMCD.

Manufacturer's Name: Agilent Technologies, Inc.
Automation Solutions Division
5301 Stevens Creek Boulevard
Santa Clara, California 95051
USA

Manufacturer's Address:

Declares under sole responsibility that the product as originally delivered

Product Name & Function: _____
Model & Part Numbers: _____
Product Options: _____
Serial Number: _____

is incomplete machinery and must not be put into service until the machinery into which it is to be incorporated has been declared in conformity with the provisions of Machinery Directive 2006/42/EC. This equipment complies with all applicable EHSRs in Annex I, except clauses _____, and _____, (but cannot in itself perform a specific application) and is required to be installed and used only as part of a complete system.

Agilent Technologies also hereby declares that these models comply with the essential requirements of the following European Directives:

EMC Directive 2004/108/EC

and conform with the following product standards:

EMC: IEC 61326-1:2005 / EN 61326-1:2006
Safety: IEC 61010-1:2001 / EN 61010-1:2001

Relevant technical documentation is compiled in accordance with part B of Annex VII of the Machinery Directive. Agilent undertakes to transmit, via email, relevant information on the partly completed machinery in response to a reasoned request by national authorities.

Contact established in the Community authorized to compile the technical file or the relevant technical documents:

Agilent Technologies Deutschland GmbH
Herrenbergerstrasse 130
71034 Boblingen
Germany

Supplementary Information:

The products were tested in a typical configuration with Agilent Technologies test systems.

This Declaration of Incorporation applies to above-listed products placed on the EU market after:

Date Location <Name>
<Title>

Conclusion

So the steps to compliance with the Machinery Directive are:

- Decide if your product falls under the MD.
- Decide if you will be the Manufacturer.
- Create a Risk Assessment and reiterate as necessary.
- Document the safety evaluation and testing.
- Compile other required documentation, including instructions.
- Create the Declaration of Conformity (or Incorporation).
- Ensure documents are translated and sent as required.
- Stop worrying ... and love the Machinery Directive?

Required reading

Machinery Directive (2006/42/EC): http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_157/l_15720060609_en00240086.pdf

MD Guide (2nd edition):
http://ec.europa.eu/enterprise/sectors/mechanical/files/machinery/guide-appl-2006-42-ec-2nd-201006_en.pdf

List of standards under the MD giving “presumption of conformity”: http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/machinery/index_en.htm

And in conclusion ...

Any questions?