

ESS approach and support for Declaration of Conformity & CE-marking

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BI Forum

2018-11-20

1. **Background**
 - a) **Legislation**
 - b) Generic Declaration of Conformity Process
2. ESS Conformity approach – step by step to compliance
 - a) Classification (incl. directives and standards)
 - b) Conformity inspection
 - c) Technical File incl. risks analysis and manual
 - d) Declaration and CE-mark
3. Next step

1. Background

a) Legislation

Legislation

By issuing and signing a Declaration of Conformity, a manufacturer assumes responsibility for the compliance of the product to **applicable legislation (directives)**.

The purpose is to meet high safety, health, and environmental protection requirements.



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Preliminary
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EU DECLARATION OF CONFORMITY	
Manufacturer/authorised representative	
We hereby declare that the following work equipment:	
Denomination/make:	
Type:	
Serial number:	
Year of manufacture:	
conforms to the following directives:	<input type="checkbox"/> Machinery Directive 2006/42/EC <input type="checkbox"/> Pressure Equipment Directive 2014/68/EU <input type="checkbox"/> <input type="checkbox"/>
Comment:	
The following standards were applied:	
The person appointed to manage the technical file is (name and address):	
Position:	<input type="checkbox"/> External supplier (In-kind / Supplier) <input type="checkbox"/> ESS Authorised person
Name, date & signature:	

1. Background

a) Legislation

CE Marking Directives

There are over 20 pieces of CE marking Legislation (Directives & Regulations) in EU. If one or more applies to a product, it is a legal requirement (in most cases) to CE mark it.

Which Legislation applies to my Product?

Each Legislation (Directive or Regulation) has a scope, which describes in detail the type of product to which it applies. E.g. for the [Machinery Directive](#), a product is only a machine if it has “moving parts”.

Most common/expected Directives in the ESS project

[Machinery Directive 2006/42/EC](#)

[Low Voltage Directive 2014/35/EU](#)

[Electromagnetic Compatibility Directive 2014/30/EU](#)

[Pressure Equipment Directive 2014/68/EU](#)

What if no CE Marking Legislation applies?

My product does not fall within the scope of any of the Directives; do I still need to CE mark my product? No! It is illegal to incorrectly CE mark your product to do so when the product does not fall within the scope of any of the CE Directives.



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1. Background

b) Generic DoC process

Generic Declaration of Conformity process (used if addressing DoC already from the design start)



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2. Approach – step by step to compliance*

a) Classification (incl. directives and standards)

1. Define the scope, needed to identify correct directives:
 - a) What is the equipment and its interfaces? E.g. a cryomodule, a cavity inside a cryomodule. Is the beam diagnostic instrument included?
2. Identify applicable directives and standards
 - a) Identify directives, regulations and national legislation
 - b) Identify associated standards, these are used to facilitate (not mandatory) compliance with the applicable directives. “Products manufactured in compliance with harmonized standards benefit from a presumption of conformity with the corresponding essential requirements”.
3. ESS WP and regulatory expertise can support with these actions. The outcome is documented in the “Technical file document” and the “Declaration of Conformity”.



*Procedure in cooperation and support by ESS (unless the in-kind partner want to proceed and do the Declaration of Conformity by own process). Learnings has been made from the Ion-source & LEBT work.

2. Approach – step by step to compliance

a) Classification (incl. directives and standards)



Example from the Cryomodule identification

CE Directives

- a) Machinery Directive 2006/42/EC
 - (Low Voltage Directive LVD 2014/35/EU – included in the MD)
- b) Electromagnetic Compatibility Directive 2014/30/EU
 - For fixed installations, hence simplified to “good engineering practice”.
- c) Pressure Equipment Directive 2014/68/EU
 - SEP (Art 4.3) is applicable

EU Regulations

- d) CLP Regulation/1272/2008 - Marking of pipes & vessels

Swedish Legislation*

- a) SFS 2017:218 Elsäkerhetsförordning (Swedish Electrical Safety Ordinance)
 - ELSÄK-FS 2008:1 (Design for electrical installation)

*A part from CE-legislation, national legislation has to be fulfilled. Implemented through inspection process with action on possible deviations.

2. Approach – step by step to compliance

a) Classification (incl. directives and standards)

Examples of Cryomodules primary recommended standards*

- a) **MD: IEC 60204-1 Safety of Machinery – Electrical equipment of Machines**
- b) **PED Vessels & Accessories**
- EN 13458-2&2 Cryogenic vessels - Static vacuum insulated vessels. Part1 Fundamental requirements. Part 2: Design, fabrication, inspection and testing.
 - EN 21013 Cryogenic vessels – Pressure relief accessories for cryogenic service.
 - EN 1626:2008 Cryogenic vessels – Valves for cryogenic service
 - EN 1797 Cryogenic vessels – Gas/material compatibility.
 - EN 13445 Unfired pressure vessels, part 1-5 - rules for the design, fabrication, and inspection of pressure vessels.
- c) **PED Material**
- EN ISO 21028-1:2017, Cryogenic vessels – Materials – Part 1: Toughness requirements for temperatures below –80 °C.
- d) **PED Manufacturing, Welding & Testing**
- EN 15614-1 Specification and qualification of welding procedures for metallic materials.
 - EN ISO 9606; Qualification test of welders – Fusion Welding (part depending on material)
 - EN ISO 9712, Qualification and certification of NDT personnel.
 - EN 5817 Fusion-welded joints in steel, nickel, titanium and their alloys.
 - EN 12300 Cryogenic vessels, cleanliness for cryogenic service.

*Used to facilitate (not mandatory) compliance with the applicable directives. Blue book: “Products manufactured in compliance with harmonized standards benefit from a presumption of conformity with the corresponding essential requirements”.

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2. Approach – step by step to compliance

b) Conformity inspection

To know what is needed to reach compliance, ESS can support with a “conformity inspection”. I.e. comparing current equipment and documentation with identified directives, regulations and standard requirements.

- a) The directives contain “essential safety requirements”, to be fulfilled for achieving compliance.
- b) ESS regulatory expertise can check the equipment and documentation (0,5-1 day exercise) and identify possible “gaps”, to be mitigated.
- c) Defined actions will then be carried out by the in-kind partner, with ESS support upon need.

#	Project/Task	Status	Description	Task owner	Due-date	Remark	Prio		
ATEX									
1	Risk Assessment	Done	Risk assessment for the ATEX part, acc. To AFS 2003:3	Helen Roser	Done	Larrys comments in blue Consider 2014/34/EU the swedish legislation AFS 2016:4 and ELSÄK-FS 2006:4. Helen understand the assignment och the content and will deliver according to schedule. Including TF for Zon 1 & 2 or both combined. FSS.0333368	1		
2	Explosion protection document					Fredrik understand the assignment och the content and will deliver according to schedule after he get the document according to item 1 & 2. First review not approved by Fredrik Jörud, a actionplan will be formed by Alejandro. All actions needs to be closed at 28th November 2018, then fredrik will do a new review. With this conditions Fredriks is ready to approve the ATEX.	1		
3	Enclosure, Design		Acc. AFS 2003:3 §13	Fredrik Jörudd	29th Aug.				
4	Enclosure, Installation		EMC / LVD / High voltage						
6	Evaluation report	Done		Roland Lundberg / Jörgen Mattson	Done		2		
7	Compiling missing documentation	Done		Øystien Midttun / Conny Wendt	Done		2		
8	Review of documentation	Done		Roland Lundberg / Jörgen Mattson	Done	Review done, Roland will close some issues and give us a recommendation on how to proceed with the deviations.	2		
w	22)Mechanical sharp edges: The main incoming cable and fiber cables is going through a tight bend and there is a risk of damage to the insulation due to a sharp edge on the metallic access hole.					<input type="checkbox"/>	<input checked="" type="checkbox"/>	2	
i	9)Grounding of LEBT not performed					<input type="checkbox"/>	<input checked="" type="checkbox"/>	2	
PED 2014/68/EC (Pressure Equipment Directive)							Yes	No	Grade
Marking of pipes and hoses according to CPL - regulation							<input type="checkbox"/>	<input checked="" type="checkbox"/>	2

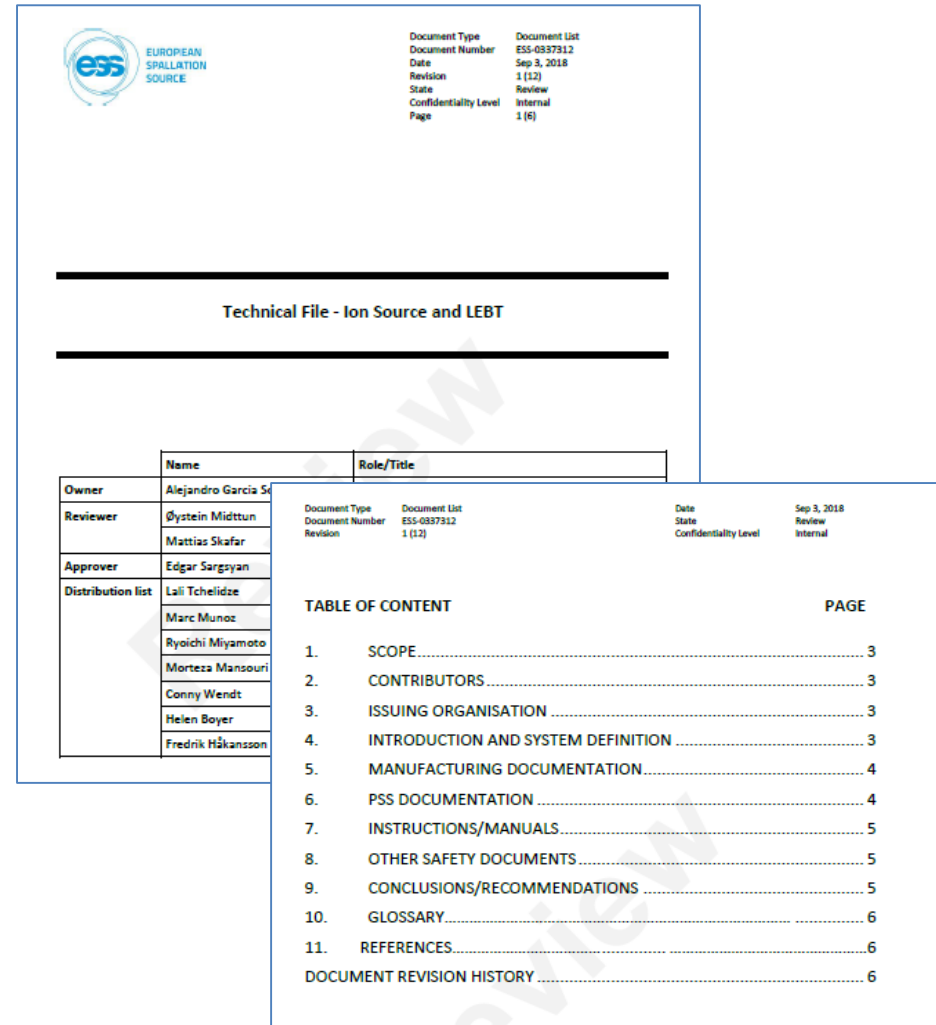
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2. Approach – step by step to compliance

c) Technical File incl. risks analysis and manual

3. Compile documentation in the “Technical file”

- a) The technical file contains or references to all documentation needed for the Declaration.
- b) ESS can explain/guide about the needed content (*should be nothing or marginally new to what is already agreed in the Technical Annex*) incl. template/examples.
- c) (So far ESS have seen the largest deviation in the risk-analysis and operation/maintenance manual.)
- d) ESS can further support the Technical File by reviewing documents and answering regulatory questions.



The image shows a document cover page for 'Technical File - Ion Source and LEBT'. It includes the ESS logo, document metadata, a distribution list, and a table of contents.

Document Metadata:

Document Type	Document List
Document Number	ESS-0837312
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Revision	1 (12)
State	Review
Confidentiality Level	Internal
Page	1 (6)

Technical File - Ion Source and LEBT

Distribution List:

Name	Role/Title
Alejandro Garcia S...	Owner
Öystein Midttun	Reviewer
Mattias Skafar	Reviewer
Edgar Sargzyan	Approver
Lali Tchelidze	Distribution list
Marc Munoz	Distribution list
Ryoichi Miyamoto	Distribution list
Morteza Mansouri	Distribution list
Conny Wendt	Distribution list
Helen Boyer	Distribution list
Fredrik Håkansson	Distribution list

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2. Approach – step by step to compliance

c) Technical File incl. risks analysis and manual

Technical file – example from the Ion-source & LEBT

1. SCOPE

This technical file document contains references to the required documentation for the Declaration of conformity according to relevant EU Directives.

2. CONTRIBUTORS

Alejandro Garcia Sosa, Øystein Middtun, Edgar Sargsyan, Fredrik Håkansson.

3. ISSUING ORGANISATION

European Spallation Source (ESS).

4. GENERAL DESCRIPTION

[ESS-0159957](#) – Technical Description of the ESS Normal Conducting Front End

4.1. SYSTEM DEFINITION

This specific system named the “Ion Source and LEBT” consists of the components within the blue boxes in Figure 1.

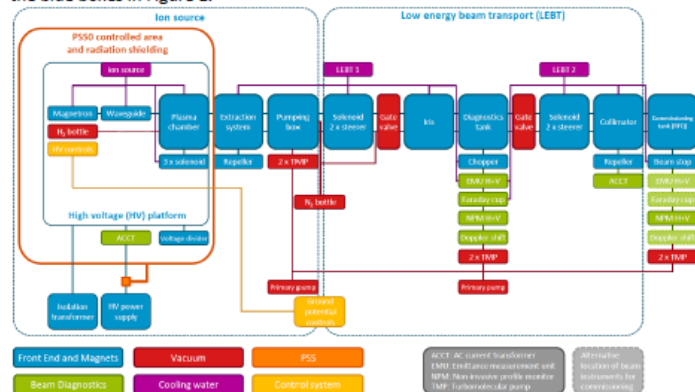


Figure 1. Block diagram of the Ion Source and LEBT at ESS.

5. OVERALL AND DETAILED DRAWINGS INCLUDING SAFETY CALCULATIONS AND TESTS

5.1. Requirement Specification

[ESS-0057828](#) – ISRC & LEBT L2 requirements

[ESS-0057834](#) – LEBT L3 Top down Vacuum requirements

[ESS-0057837](#) – PBI Interface Requirements for LEBT

5.2. Layout Ion Source/LEBT

[ESS-0337929](#) – Ion Source + LEBT Layout

5.3. Overall Flowchart (water cooling)

[ESS-0059672](#) – Overview P&ID of tunnel cooling system for IS/LEBT/MEBT and DTL FCs

5.4. Electrical Diagram

[ESS-0288126](#) – Ion Source and LEBT grounding System

[ESS-0323111](#) – HV Rack Schematics

[ESS-0323115](#) – Ion Source- Rack-III Schematics

[ESS-0323118](#) – Ion Source- Rack-IV Schematics

[ESS-0323120](#) – Isolation Transformer Signals

[ESS-0136167](#) – PLATFORM POWERING LOGICAL CONNECTION SCHEMATICS

5.5. Detailed Drawings

[ESS-0401438](#) – ISrc & LEBT Assembly

5.6. Safety inspection, test and calculations

[ESS-0380466](#) – Pre-SRR Report/Deviation & Action plan

[ESS-0122281](#) – Ion source safety fence

[ESS-0317305](#) – Ion source and LEBT verification plan

6. RISK ASSESSMENT & PROTECTIVE MEASURES

6.1. Risk assessment

[ESS-0118213](#) – Hazards of the ion source and LEBT

2. Approach – step by step to compliance

c) Technical File incl. risks analysis and manual

Technical file – example from the Ion-source & LEBT

6.2. Concept document for the personnel safety system

[ESS-0217911](#) – Concept Document for the Personnel Safety System 0

6.3. Scope document for accelerator personnel safety system

[ESS-0237881](#) – Scope Document for Accelerator Personnel Safety System 0

6.4. IEC 61508 hazard and risk analysis document for PSS

[ESS-0229506](#) – IEC 61508 Hazard and Risk Analysis Document for PSSO

6.5. Overall safety requirements and their allocation document for PSS

[ESS-0231390](#) – Overall Safety Requirements and their Allocation Document for PSSO

7. ASSOCIATED STANDARDS AND REGULATIONS

7.1. Standards

The following standards have been used:

IEC 61508:2010 part 1 - 7 - Functional Safety of electrical/electronic/programmable electronic safety-related systems

IEC 61511:2016 part 1 - Functional safety - Safety instrumented systems for the process industry sector - Part 1: Framework, definitions, system, hardware and application programming Requirements

SS-4364000 - Low-voltage electrical installations - Rules for design and erection of electrical installations

SS-EN 50110-1:2013 - Operation of electrical installations – Part 1: General requirements

7.2. Other laws & regulations

The system conform to the following Swedish laws, regulations and provisions:

SFS 2017:218 - Swedish Electrical Safety Act

ELSÄK-FS 2008:1 - Execution of electrical installations (High voltage)

AFS 2017:3 - Use and control of pressurized devices

AFS 2023:3 - Work in a potentially explosive environment

8. INSTRUCTIONS/MANUALS

8.1. Commissioning

[ESS-0337871](#) – Operating Instructions High Voltage Power Supply.

[ESS-0288183](#) – Operating instructions High voltage insulation three phase transformer.

8.2. Operators (control room)

[ESS-0259919](#) – INFN Operational Manual ISRC & LEBT

8.3. Operators (technician)

[ESS-0288215](#) – INFN Maintenance Manual ISRC & LEBT

8.4. Maintenance and spare parts

[ESS-0290888](#) – PSSO Maintenance Manual.

[ESS-0135817](#) – Insulator for ESS platform.

[ESS-0135818](#) – HVR-969 High Voltage Resistors Metallux Datasheet.

[ESS-0217253](#) – Pink Tube Datasheet.

[ESS-0136018](#) – FuG C 2124 High Voltage cables Datasheet.

[ESS-0288257](#) – Ametek SGA CoC Factory Calibration Material Contents Declaration.

[ESS-0217261](#) – Ametek XG 1500 Steerer power supply Certificate of Conformance.

9. OTHER SAFETY DOCUMENTS

9.1. Other test certificates regarding environmental safety

[ESS-0140760](#) – The ISRC systems shall designed to be compatible with the ambient air temperature, including as a function of time.

[ESS-0140749](#) – The ISRC system and its subsystems shall be designed to be compatible with operation within the humidity conditions of the tunnel.

[ESS-0056725](#) – Environmental requirements for installation of ISRC & LEBT in tunnel

10. DECLARATION OF CONFORMITY

10.1. System declaration

[ESS-0371959](#) – EU Declaration of Conformity - ISrc & LEBT

2. Approach – step by step to compliance

c) Technical File incl. risks analysis and manual

Technical file – as written in the Machinery Directive

The technical file shall comprise the following:

- 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,
- 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,
- 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 authorized representative,
- a copy of the instructions (manual) for the machinery,
- 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,
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2. Approach – step by step to compliance

d) Declaration and CE-mark

4. Produce Declaration of Conformity and CE-mark

- a) When the conformity-inspection is mitigated and the technical file is accomplished, the “Declaration of Conformity” can be signed by the in-kind partner’s “responsible person” (someone who has the power to make binding commitments on behalf of the manufacturer). ESS can provide a template of the Declaration if wanted.
- b) (For limited smaller deliveries the DoC can instead be a “Partly completed machinery” or similar.)
- c) The Declaration should preferably be accomplished before the ESS beam commissioning, to assure that the equipment is safe.
- c) When the Declaration is signed, the CE-mark can be affixed on the equipment (if applicable).



EUROPEAN
SPALLATION
SOURCE

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2. Approach – step by step to compliance

d) Declaration and CE-mark

**Done – with Declaration of
Conformity!**

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3. Next step

ESS is currently establishing communication channels to all in-kind partners via the work packages and then:

- a) An ESS regulatory representative will be allocated to the WP for supporting the work.
- b) The detailed process (as presented in previous slides) will be agreed on, started and tracked to make sure “safety” is achieved and proved in due time.
- c) The work will be prioritized in “installation/commissioning order”

3. Next step

ESS Support Team:



Mattias Skafar
Head of Quality Division



Conny Wendt
Quality CE-Lead



Fredrik Håkansson
AD CE Responsible



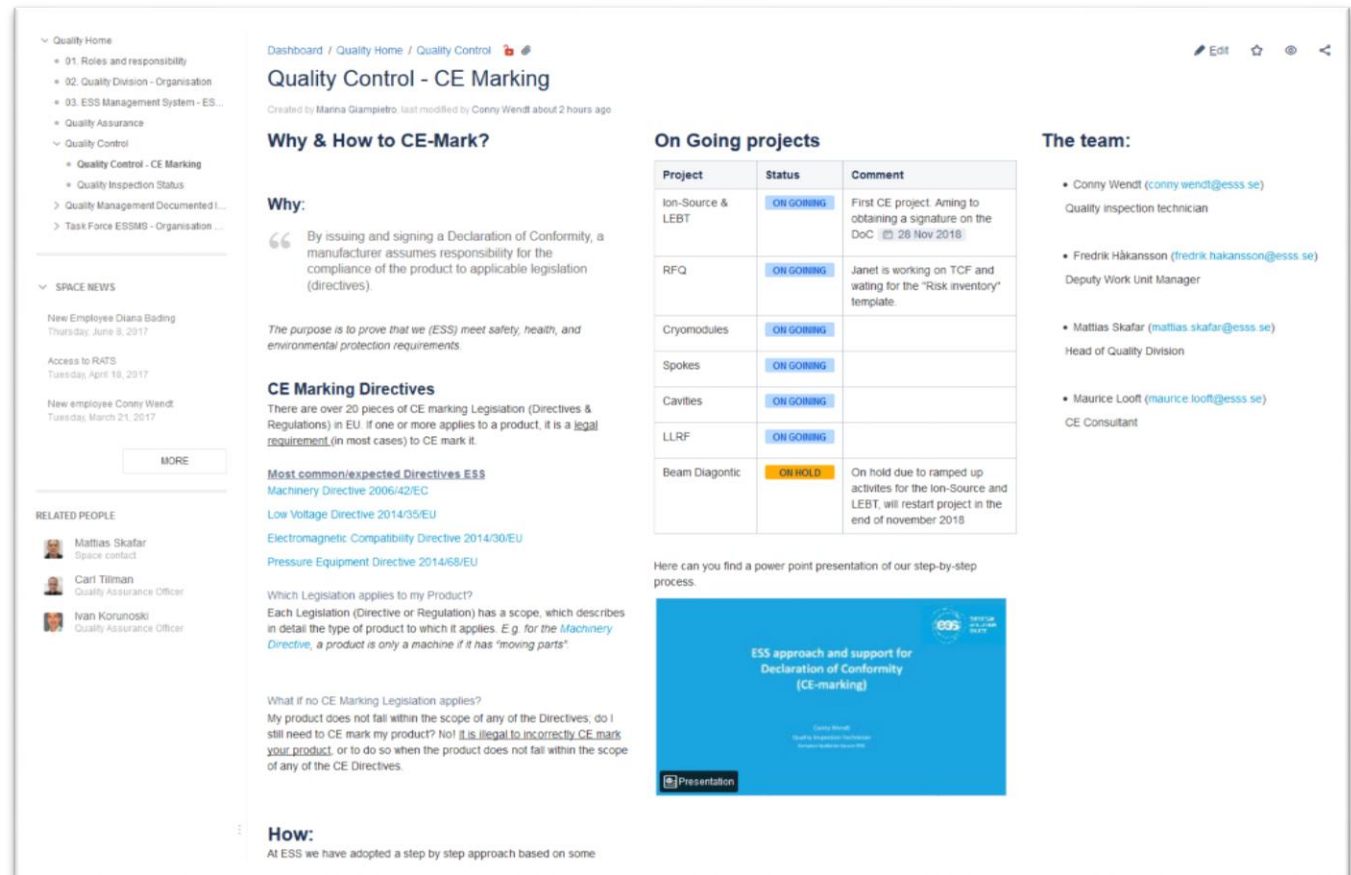
Larry Falk
CE Expert



Maurice Looft
CE Expert

3. Next step

A web site is currently being established to contain more information regarding CE-marking



Dashboard / Quality Home / Quality Control

Quality Control - CE Marking

Created by Marina Giampietro, last modified by Conny Wendt about 2 hours ago

Why & How to CE-Mark?

Why:

By issuing and signing a Declaration of Conformity, a manufacturer assumes responsibility for the compliance of the product to applicable legislation (directives).

The purpose is to prove that we (ESS) meet safety, health, and environmental protection requirements.

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Most common/expected Directives ESS

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How:

At ESS we have adopted a step by step approach based on some


On Going projects

Project	Status	Comment
Ion-Source & LEBT	ON GOING	First CE project. Aiming to obtaining a signature on the Doc. 26 Nov 2018
RFQ	ON GOING	Janet is working on TCF and waiting for the "Risk inventory" template.
Cryomodules	ON GOING	
Spokes	ON GOING	
Cavities	ON GOING	
LLRF	ON GOING	
Beam Diagnostic	ON HOLD	On hold due to ramped up activities for the Ion-Source and LEBT. will restart project in the end of november 2018

The team:

- Conny Wendt (conny.wendt@ess.se) Quality inspection technician
- Fredrik Håkansson (fredrik.hakansson@ess.se) Deputy Work Unit Manager
- Mattias Skafar (mattias.skafar@ess.se) Head of Quality Division
- Maurice Looft (maurice.looft@ess.se) CE Consultant

Here can you find a power point presentation of our step-by-step process.



ESS approach and support for Declaration of Conformity (CE-marking)

Conny Wendt
Quality Inspection Technician
conny.wendt@ess.se

Presentation

Thank You!

Questions?