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EXTERNAL REFERENCE

F4E Document

F4E-QA-135 Supplier CE Marking Requirements

This document defines general requirements for CE Marking.

<i>Approval Process</i>			
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Change Log

F4E-QA-135 Supplier CE Marking Requirements (2CK5ZZ)

<i>Version</i>	<i>Latest Status</i>	<i>Issue Date</i>	<i>Description of Change</i>
v0.0	In Work	07 June 2018	
v1.0	Signed	21 August 2018	Document uploaded.
v2.0	Approved	15 October 2018	Legal and POI comments addressed.



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Control Page

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Document title	Supplier CE Marking Requirements
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Areas and functions	
Process ownership:	F4E Director
Area(s) concerned:	F4E Contracts F4E Manual (Operational)
Function(s) concerned:	F4E Suppliers All F4E Operational Roles

Purpose

This document defines general requirements for CE Marking.

Scope

This document is applicable to all operational procurements and grants contracted by F4E.

Applicable Documents

[1] F4E-QA-115 Supplier Project Management and Quality Requirements (F4E_D_22F8BJ)

Abbreviations and Definitions

EC / EU	European Community / European Union
Contract	Has the meaning defined in Section "Abbreviations and Definitions" of [1]
F4E	Fusion for Energy, has the meaning defined in Section "Abbreviations and Definitions" of [1]
FDR	Final Design Review, has the meaning defined in Section in "Abbreviations and Definitions" of [1]
MRR	Manufacturing Readiness Review, has the meaning defined in Section "Abbreviations and Definitions" of [1]
ITER IO	Has the meaning defined in Section "Abbreviations and Definitions" of [1]
Supplier	Has the meaning defined in Section "Abbreviations and Definitions" of [1]
Subcontractor	Has the meaning defined in Section "Abbreviations and Definitions" of [1]

General requirements for CE Marking

F4E-QA-135-01	<p>The Supplier shall determine EC/ EU Directives and/or Regulations requiring CE Marking that apply to components/equipment/assemblies in the scope of Contract.</p> <p>For information, the main EC/EU Directives and Regulations applicable to the scope of F4E Contracts are:</p> <ul style="list-style-type: none"> ▪ Machinery Directive 2006/42/EC ▪ Pressure Equipment Directive 2014/68/EU ▪ Electromagnetic Compatibility Directive 2014/30/EU ▪ Low Voltage Directive 2014/35/EU ▪ Equipment and Protective Systems intended for use in Potentially Explosive Atmospheres (ATEX) Directive 2014/34/EU ▪ Lifts Directive 2014/33/EU ▪ Construction Products Regulation (EU) No 305/2011
F4E-QA-135-02	<p>The Supplier, or Subcontractor(s), is considered the Manufacturer of components/equipment/assemblies in the scope of Contract. The Supplier, or Subcontractor(s), shall perform Conformity Assessment, affix the CE Marking and issue EC/EU Declaration(s) of Conformity where EC/ EU Directives and/or Regulations that require CE Marking apply.</p> <p>Remark: This requirement applies to all Contracts, including those that do not include design, e.g. "Built-to-Print"/ "Manufacturing only", etc.</p>
F4E-QA-135-03	<p>The Supplier shall deliver components/equipment/assemblies certified and CE marked at the highest possible integration level, i.e. at the level of independent functional units (assemblies).</p> <p>Neither F4E nor the Plant Operator (ITER IO or Consortio RFX) perform certification/ CE marking or integration under national legislation of components/ equipment/ assemblies included in the Supplier's scope of Contract unless otherwise specified in the Contract.</p> <p>Remark: Equipment/assemblies composed of CE marked components also require Conformity Assessment and CE marking on equipment/assembly level.</p>
F4E-QA-135-04	<p>The Supplier shall ensure that sub-contracted or purchased components/equipment/assemblies comply with EC/ EU Directives and/or Regulations that require CE Marking where applicable.</p> <p>This includes verifying CE Marking, EC/EU Declarations of Conformity and operating and maintenance instructions.</p>
F4E-QA-135-05	<p>Where the scope of Contract includes components/equipment/assemblies creating potentially explosive atmospheres during operation or maintenance (e.g. by releasing flammable gases or vapours in sufficient quantities) or is specified to operate in potentially explosive atmospheres (e.g. where flammable gases or vapours are present in sufficient quantities due to other sources) the Supplier shall ensure that activities related to explosion protection are carried out by personnel with sufficient qualification and experience.</p>

F4E-QA-135-06	<p>The Supplier shall provide the following documents for F4E's review and acceptance:</p> <ol style="list-style-type: none"> 1. Results of Supplier's analysis regarding applicability of EC/EU Directives and/or Regulations to the scope of Contract and a CE Marking strategy for the complete scope of Contract at the level of independent functional units (assemblies): <ol style="list-style-type: none"> 1.1. In case of Contracts including Design: As part of the Design Report or separate document at the FDR. 1.2. In case of Contracts not including Design: At the MRR. 2. Manufacturer's EC/EU Declaration(s) of Conformity, and, if applicable, documents issued by Notified Bodies in the course of Conformity Assessment latest 15 working days prior to the transfer of ownership to F4E (if not otherwise specified in the Contract). 3. Operating and maintenance instructions in English and in the national language of the country of destination latest 15 working days prior to the transfer of ownership to F4E (if not otherwise specified in the Contract). [1], Section 8.9, provides assistance on instructions for machinery. Operating and maintenance instructions in French are waived for components/equipment/assemblies whose place of delivery is the ITER Site, Cadarache, France. 4. Emissions and immunity test reports of apparatus intended for incorporation into a particular Fixed Installation and otherwise not made available on the EU market according to Art. 19 of Directive 2014/30/EU, Electromagnetic Compatibility, latest 15 working days prior to the transfer of ownership to F4E (if not otherwise specified in the Contract). 5. Upon request, technical documentation related to hazard identification, risk evaluation and risk mitigation of the component/equipment/assembly. 6. Upon request, other technical documentation related to design, manufacturing and erection of the component/equipment/assembly as necessary for integration into a higher level assembly and Conformity Assessment by another party.
F4E-QA-135-07	<p>Under certain conditions, the Directives 2006/42/EC on Machinery, Art. 1(2)(c), and 2014/68/EU on Pressure Equipment, Art. 1(2)(h), exclude items for nuclear use from their applicability. If the Supplier considers that the scope of Contract falls, partially or entirely, under these exclusions, the Supplier shall:</p> <ul style="list-style-type: none"> ▪ Submit to F4E a technical justification substantiating the applicability of the exclusion, ▪ Request F4E's acceptance. <p>In case that no acceptance is granted by F4E, CE Marking applies.</p> <p>The same applies for any other exclusion from any EC/EU Directive or Regulation requiring CE Marking deemed applicable by the Supplier.</p>

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