MAX IV CE marking process

1. Purpose and scope

The purpose of this document is to describe the requirements, responsibilities and procedures for CE marking of any equipment manufactured by MAXIV that falls under the Machine directive.

2. Mandatory requirements

The CE mark is a mandatory European marking for machinery and equipment to indicate conformity with the essential health and safety requirements set out in European Directives.

For the purposes of the Machine directive, machinery means an assembly consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application.

At MAXIV, all machine related equipment must comply with the Machine directive 2006/42/EC and be CE marked (unless it is a temporary laboratory equipment).

At MAXIV, we are responsible for that all applicable essential health and safety requirements from the directive and from related harmonized standards is fulfilled for all machine related equipment.

To permit the use of a CE mark on a machine, proof that the item meets the relevant requirements must be documented. This routine will describe how we fulfill all mandatory requirements.

3. Description of the CE marking procedure

When an equipment that falls under the Machine directive is planned to be made, the responsible person must address the Safety group to get information of what kind of action that must be considered.

This is the responsibility for the machine safety group, it will also include other safety groups (Radiation, Fire, Chemical and Experimental safety).

it is important that the machine safety group is involved in the process as early as possible,
as the conditions for machine safety can greatly affect project-related issues.

A risk assessment will be written, this special machinery assessment is based on the standard: EN ISO 12100 Safety of machinery – General principles for design – Risk assessment and risk reduction.

The principal terms for this assessment are:

(a) determine the limitations of the machine, which includes its intended use and any foreseeable misuse; of the same;

b) identify the sources of risk and associated risky situations;

c) estimate the risk for each identified source of risk and risky situation;

d) evaluate the risk and decide on the need for risk reduction;

(e) eliminate the source of risk or reduce the risk associated with the source of risk by means of protective measures.

This is not the same risk assessment that are normally used at MAXIV and it is handled by the machine safety engineer.
A template for the risk assessment (D_H_SA_MS_RA_ Machine Directive risk assessment template) can be found at:
https://sharepoint.lu.se/sites/maxiv_document-management-system/D/Forms/AllItems.aspx?id=%2Fsites%2Fmaxiv%5Fdocument%2Dmanagement%2Dsystem%2FD%2FH%2FSA%2FMS%2FRA

The task of completing the risk assessment is something that will involve many people as no single person can be assumed to have the best answer to all the different risk issues that will arise.
Therefore, it is important to have a broad representation of people with different skills included in this work.

In parallel to this work, a manual for the machine that describes how to handle the machine in a safe way, must be written. The manual must be written in English and Swedish.

A template for the manuals (D_H_SA_MS_RA_English manual template for CE marked equipment manufactured @ MAXIV) can be found at:
https://sharepoint.lu.se/sites/maxiv_document-management-system/D/Forms/AllItems.aspx?id=%2Fsites%2Fmaxiv%5Fdocument%2Dmanagement%2Dsystem%2FD%2FH%2FSA%2FMS%2FRA

When all the determined action from the risk assessment is conducted, tested and verified, the technical file should be compiled.
The technical file represents a set of documents that demonstrate the conformity of a product with the CE-marking legislation. The documentation must specify the applicable product safety requirements and cover the design, manufacture, and operation of the product.

The place where the technical file can be found is in the sharepoint MAXIV management site under the beamlines specific map structure (example C_T_B310A – that is The CoSAXS beamline).

Next thing is to make and sign the declaration of conformity.

The declaration of conformity is a formal declaration by a manufacturer that the product to which it applies meets all relevant requirements of all product safety directives applicable to that product.
It is a sign that a product has been designed and constructed for compliance with relevant essential requirements, and has been through the appropriate conformity assessment processes.

The declaration of conformity must include:

List the correct and applicable Legislative & standards.

Ensure correct standard numbers with prefixes are stated. Some Directives/Regulations also require the version of the standard to be listed too.

The Declaration should not mislead or create confusion (e.g. to only list the standards for which evidence of conformity has been retained).

The person signing should be of an appropriate and relevant position in the company.

The declaration must be signed.

The correct date must be used, for example the date of signature should not predate any of the standards or Legislation stated.

A template for the declaration of conformity (D_H_SA_MS_RA_ EU declaration of conformity template.docx) can be found at:
https://sharepoint.lu.se/sites/maxiv_document-management-system/D/Forms/AllItems.aspx?id=%2Fsites%2Fmaxiv%5Fdocument%2Dmanagement%2Dsystem%2FD%2FH%2FSA%2FMS%2FRA

EC DECLARATION OF CONFORMITY

We

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Ensures under your own responsibility that the machine with type designation

CoSAXS flight tube manufacturing number 1

covered by this assurance is in accordance with the following standards or other regulatory documents:
EN ISO 12100: 2010 Risk assessment and risk reduction

and complies with all applicable provisions under the terms of
Machine Directive MD (2006/42 / EC)
Pressure Vessel Directive PED (2014/68 / EU)
Low Voltage Directive LVD (2014/35 / EU)
Electromagnetic compatibility EMC (2014/30 / EU)
Artificial optical radiation (2006/25 / EC)
Radiation Protection Act (2018: 396) / Radiation Protection Directive (2013/59 / EURATOM)

Date

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A copy of the declaration of conformity must be included in the manual.

After all this is completed, the CE mark can be affixed on the machine.
The mark must be visible, easy to read and indelible.
The CE marking shall consist of the initials "CE": both letters shall have the same vertical dimension and shall not be less than 5 mm.

A template for the sign (D_H_SA_MS_RA_ D_H_SA_MS_RA_Template for CE marking sign.docx) can be found at:
https://sharepoint.lu.se/sites/maxiv_document-management-system/D/Forms/AllItems.aspx?id=%2Fsites%2Fmaxiv%5Fdocument%2Dmanagement%2Dsystem%2FD%2FH%2FSA%2FMS%2FRA

4. Definitions and abbreviations

N/A	Not applicable

5. References

The Machine directive 2006/42/EC
EN ISO 12100 Safety of machinery – General principles for design – Risk assessment and risk reduction

6. Documentation

Document revision history

Date	Remark	Revision	Prepared by
2022-01-21	Document created	N/A	Hasse Andersson
2022-01-26	First version	001	Hasse Andersson
2022-02-09	Update after RM review	002	Hasse Andersson
2022-03-09	Updated format in accordance to Radiaton safety standard.	003	Hasse Andersson
2023-05-08	Updated links	004	Hasse Andersson

7. Distribution list

Distributed to	**Division**	**Group**
All managers	Max IV Laboratory	All groups
Safety staff	Director	Safety