

Document title Guideline for purchasing machines at MAX IV	Document location B_H_SA_MS	
Prepared by Hasse Andersson	Date 2024-04-17	Revision 1.1
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Reviewed by	Date
Billian Assenov	2023-08-16
Rema Malar	2023-10-03

Guideline for purchasing machines at MAX IV





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1 Purpose

The purpose of this document is to describe the recommended process when purchasing machines and machine safety related equipment at MAX IV.

2 Scope

This guideline is valid at purchasing processes for all kind of machines and equipment that is covered by the machine directive 2006/42/EC or the machinery regulation (EU) 2023/1230 (replacing the machine directive and becoming mandatory from 20 Januari 2027).

See chapter 6.2 for a detailed explanation.


3 Responsibilities

The machine safety engineer is responsible for providing information, guidelines, and technical support in the purchasing process.

The project managers are responsible for implementing this guideline recommendations in the project process.

All persons involved in processes that includes purchasing of machines and equipment must follow the recommendations in this guideline.

All group managers are responsible for communicating this guideline their respective group members prior to purchasing such equipment.

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4 Definition and abbreviations

GM Group managers

Machine directive

Machinery regulation Defines essential health and safety requirements of general application, supplemented by a number of more specific requirements for certain categories of machinery.

CE CE marking is a product marking within the European Union that shows that a product meets the necessary requirements regarding, among other things, the environment, health, and safety in order to be sold on the internal market.

Declaration of conformity A declaration of conformity is a mandatory document that the manufacturer needs to sign to declare that the product complies with the EU requirements.


Purchaser The person/team/group who intends to purchase a machine.

Robot A robot is a machine—especially one programmable by a computer—capable of carrying out a complex series of actions automatically.

Cobot A cobot, or collaborative robot, is a robot intended for direct human-robot interaction within a shared space, or where humans and robots are in close proximity.

5 References

MAX IV manuals, procedures and plans	Location
Machine directive 2006/42/EC	https://eur-lex.europa.eu/
Machinery regulation (EU) 2023/1230)	https://eur-lex.europa.eu/
AFS 2008:3 the Swedish Work Environment Authority's regulation on machines	www.av.se
AFS 2011:1 The Swedish Work Environment Authority's regulations on changes in AFS 2008:3	www.av.se
MAX IV CE marking process	B_H_SA_MS
Purchase policy (inkospolicy_v210102.pdf)	www.medarbetarwebben.lu.se

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6 Details

6.1 Introduction

At MAX IV, the mandatory regulation for all kind of equipment related to machines, is the machinery regulation (EU) 2023/1230 (or machine directive 2006/42/EC).

The European Machinery Regulation/Directive was introduced to establish broad safety objectives for manufacturers and distributors of a wide range of mechanical equipment.

The regulation/directive requires manufacturers to demonstrate that their products comply with the various EU regulations related to the machinery they produce.

The regulation/directive states that in order for machines to be sold within the EU, they must be CE-marked.

This procedure is a requirement regardless of whether the product is manufactured within the EU or not. The requirements for CE marking a product are different depending on the type of product, but in summary a CE marking of machines sets requirements for environmental protection, safety and health.

All machine purchased for use at MAXIV must be safe accordance with the European machinery regulation/directive, this applies for everyone that comes in contact with the machine (visitors, users, maintenance, etc).

All machines purchased or build in MAX IV should consider the following:

- Material used in the machine.
- Material produced by the machine.
- Waste produced by the machine.

Therefore, it is recommended that before a machine is purchased, the group that is responsible for the machine carries out a risk assessment with the help from the various specialist.

See chapter 6.6 for the list of MAX IV specialists.

6.2 Lund University and MAX IV requirements and recommendations for purchasing machines.

The Procurement department at Lund's university has a Purchase policy that is mandatory to follow. See chapter 5 for link to the purchase policy document.


"The purchase of the goods and services needed to run Lund University's (this includes MAXIV) operations must take place in a legal, business-like and efficient manner. By legal means that in every purchasing situation applicable law, rules and guidelines, internal as well as external, must be taken into account".

Machines used at MAXIV shall always be CE marked, if a non-CE marked machine is considered for purchasing, the manufacturer (or importer) or MAX IV must perform the CE marking themselves. This is described in the routine: B_H_SA_MS_CE marking process at MAX IV.

Machines and machine safety related equipment that are purchased to use at the beamlines is mostly planned and purchased in the projects and it's therefore critical that the review on CE marking is planned and performed during the project phase.

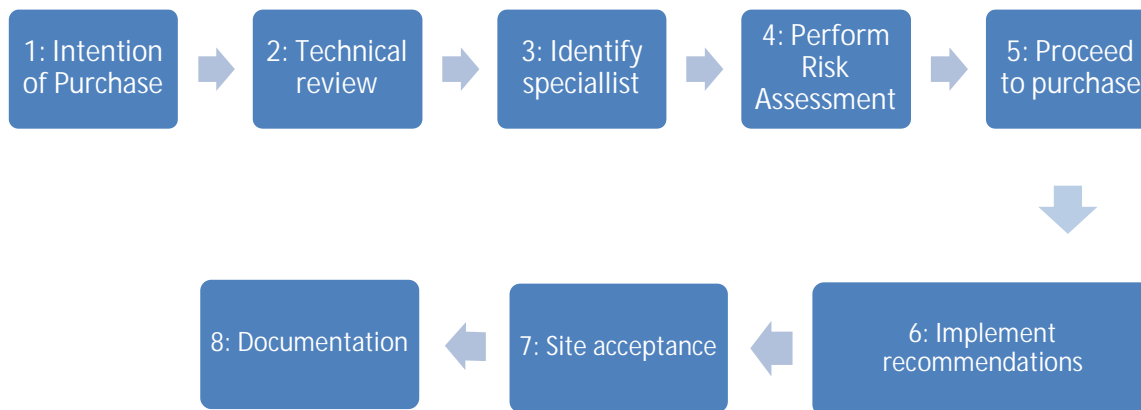
For other situations, contact the relevant specialists for review and feedback.

It is critical that the evaluation and risk assessment of the machine should be done before the purchase.

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6.3 Machine purchasing process in MAX IV

Recommended process of purchasing machines in MAX IV:



1: Intention of Purchase

When an intention of purchase is made, a purchaser should refer to the Lund University Purchasing and Procurement Departments guidelines:

<https://www.medarbetarwebben.lu.se/stod-och-verktyg/inkop-faktura-ekonomi/inkop-och-upphandling>

2: Technical Review

A purchaser conducts the technical review by:

- Review Manual
- Reviewing standards that are relevant.
- Collecting technical /performance data

3: Identify specialists

When contact is needed with any of the listed specialists (see chapter 6.6), a purchaser should contact the team leader or group manager for the specialist's group.

4: Perform Risk Assessment

The purchaser should assemble the specialists and staff with experience in the machine intended for purchase (or similar) to do the risk assessment.


The type of risk assessment can be of different types, contact the work environment engineer for guidance.

The group manager responsible for the intention of purchase is recommended to be the one who approves the risk assessment.

5: Proceed to purchase

The group manager of the purchaser where the machine is intended to be used, is the one who approves the order and assigns a person to be in charge of informing the involved persons of the progress.

Make sure that any additional recommendations in the risk assessment is communicated to the supplier of the machine.

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6: Implement Recommendation

The recommendations from the risk assessment (actions that require involvement from MAXIV personnel) should be implemented at this stage.

7: Site acceptance

A site acceptance test should be conducted by purchaser to verify whether the equipment meets and/or exceeds the functionality and performance requirements specified by the purchaser.

The site acceptance test is something that conducted for a larger or complicated machine. Please refer to the machine safety engineer for guidance.

8: Documentation

When the outcome from the tests is accepted (in relation to the purchasers' specifications), all documentation in the latest versions are collected and saved in SharePoint by the purchaser.

6.4 Explanation and examples of machines and machine safety related equipment

the machine regulation/directive defines a machine as "an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application".

This regulation/directive applies to machinery, interchangeable equipment, safety components, lifting accessories, chains, ropes and webbing, removable mechanical transmission devices and partly completed machinery as defined in Article 2/3 of the regulation/directive.

Example of things at MAX IV that counts as machine and machine safety related equipment are Elevators, vending machines, hexapods, sample changers, 3D printers, handheld equipment as drill and saw, vacuum cleaner, workshop equipment as lathe and milling machines, various lifting equipment as lifting chains/ropes/webbing.

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6.5 Mandatory documentation for a CE marked machine.

When purchasing a machine, it is crucial for the purchaser to ensure the following documentations and requirements are being met by the supplier.

1: A manual which when it is followed, makes the machine safe to operate.

2: An EC declaration of conformity where it shows what regulations/directives the machine is CE marked by.

The EC declaration of conformity must contain the following particulars:

- Business name and full address of the manufacturer.
- Name and address of the person authorized to compile the technical file.
- Description and identification of the machinery, including generic denomination, function, model, type, serial number, and commercial name.
- A sentence expressly declaring that the machinery fulfils all the relevant provisions of this regulation/directive and where appropriate, a similar sentence declaring the conformity

with

other regulations/directives and/or relevant provisions with which the machinery complies.

- Where appropriate, a reference to the harmonized standards used.
- The place and date of the declaration.
- The identity and signature of the person empowered to draw up the declaration on behalf of the manufacturer or his authorized representative.

3: A CE mark on the machine.

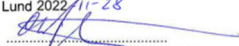
EC DECLARATION OF CONFORMITY

We
MAX IV Laboratory
Fotongatan 2, 225 94 Lund Sweden
046-222 98 72
www.maxiv.lu.se

Ensure under your own responsibility that the machine with type designation
For MAX experiment hutch equipment, as commissioned 2022-11-01

covered by this assurance is in accordance with the following standards or other regulatory documents:
EN ISO 12100: 2010 Risk assessment and risk reduction
SRVFS 2004: 7 Regulations on explosive environment when handling flammable gases and liquids.

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 (2014/30 / EU) Equipment for use in potentially explosive atmospheres, ATEX Directive (2014/34 / EU)
Radiation Protection Act (2018: 396) / Radiation Protection Directive (2013/59 / EURATOM)
Electromagnetic compatibility EMC (2014/30 / EU)


Lund 2022-11-28

Director Olof Karis, Lund Sweden

The name and address of the person authorized to compile the technical documentation is: Hans Rune Andersson, MAX IV, Fotongatan 2, 224 84 Lund Sweden
This assurance only applies to the machine in the condition the first time it was put into service and does not include components that are added and / or actions subsequently implemented



Example of declaration of conformity

Example of CE mark sign

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6.6 Mandatory documentation for a partly completed machine.

Partly completed machinery is only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery to which this regulation/directive applies.

A robot is an example of a partly completed machinery and a robot system like a sample changer is a completed system.

When purchasing partly completed machines, always contact, and follow directions from the machine safety engineer as this must be CE marked by MAXIV.

The purchaser is required to ensure the following requirements are met by the manufacturer.

For a completed machine (robot system), the following is required:

- Instructions for use;

The instructions are provided by the manufacturer.

- A DOI (Declaration of Incorporation);

The DOI is provided for incomplete or partial machines. Robots are incomplete machines.

A DOI is provided by the manufacturer to enable integrators to CE mark their robot system.

- A risk assessment of the intended use(s);

The risk assessment is made by MAXIV.

- A CE Declaration of Conformity (DOC);


The DOC is made by MAXIV

- Marking, including the CE mark, on the completed machine (robot system) according to ANNEX III;

The CE marking is made by MAXIV


- A supplier's "technical file", to be stored for 10 years.

The technical file is made by MAXIV.

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6.7 List of specialists at MAX IV

Biosafety	Experimental safety
Chemical and gas safety	Experimental safety
Controls & IT	Technical division
Cryogenic	Engineering 2
Electrical & power supply systems	Engineering 2
Ergonomics	General safety
Work environmental safety	General safety, Skyddsombud
Facility management	Administrative division
Fire safety	General safety
Laser safety	Accelerator Development
Lifting/installation	Logistics & Technical services
Machine safety	General safety
Mechanical design	Engineering 1
Piping systems	Technical Infrastructure
Pressurized air	Technical Infrastructure
Radiation	Radiation safety
Ventilation	Technical Infrastructure
Vibrations	Survey, Alignment & Mechanical stability
Water cooling	Technical Infrastructure

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6.8 Document revision history

Date	Remark	Revision	Prepared by
2022-08-05	First draft. To be internally reviewed.	0.1	Hasse Andersson
2022-08-31	Second draft for review	0.2	Hasse Andersson
2023-03-01	Updated link for MAXIV organisation	0.3	Hasse Andersson
2023-03-21	Incorporated Skyddsombud in the process	0.4	Hasse Andersson
2023-08-15	Added section whit mandatory documents	0.5	Hasse Andersson
2022-08-05	Preparation of draft document	0,6	Hasse Andersson
2023-11-27	Approval of Document	1.0	Rema Malar
2024-04-17	Added information on robots in chapter 6.6	1.1	Hasse Andersson

7 Distribution list

Distributed to	Division	Group
Procurement	Administrative division	Finance
Group managers	MAX IV Laboratory	All groups
Safety staff	Director	Safety
Project Managers	Technical division	CPO