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Supplementary document

to the

“Guide to the Machinery Directive (2006/42/EC)

– Significance for Valves”

dated May 2018

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I. Preface

This supplementary document puts the requirements of the “Guide to the Machinery Directive (2006/42/EC) – Significance for valves” dated May 2018 into concrete terms. We would like to point out that in case of doubt the statements in this supplementary document are superseded by the main document.

This supplementary document provides machine manufacturers with support for carrying out the conformity assessment procedure which machine manufacturers have to carry out in line with the requirements of article 5(1) of the Machinery Directive and document in line with the requirements of Appendix VII A. Before applying the CE mark and issuing the EC Declaration of Conformity, the manufacturer has to carry out and document the required conformity assessment procedure(s). If the Machinery Directive is applied, the conformity assessment procedure contains the following elements:

1. Determining the basic health and safety requirements in line with Appendix I of the Machinery Directive
2. Stating of the technical safety measures to meet the determined basic health and safety requirements to the current state of the art and in sequence according to Appendix I, no. 1.1.2 b
3. Carrying out and documenting the risk assessment
4. Establishing the measures for internal production control for series-produced goods
5. Creating the operating instructions taking into account the residual risks determined through the risk assessment, see Appendix I, no. 1.7.4.2
6. Creating the EC Declaration of Conformity and applying the CE mark

Note: As a rule, valves are not subject to Appendix IV of the Machinery Directive. According to the requirements of the Machinery Directive, the manufacturer has no obligation to involve an external testing agency for the conformity assessment procedure for these valves.

This supplementary document provides information

- for determining the basic health and safety requirements in line with Appendix I of the Machinery Directive
- for carrying out the risk assessment in line with the Machinery Directive

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- for implementation by the manufacturers (which can also be helpful for supporting the users with their implementation), e.g. when carrying out the conformity assessment procedure
- for creating the technical documents in line with Appendix VII of the Machinery Directive with which the manufacturer can prove the conformity of the product with the requirements of the Machinery Directive and which will remain with the manufacturer
- for changes to the documentation with respect to other guidelines (e.g. operating instructions, conformity assessment procedure)
- for the CE marking
- for the intended use (e.g. voltage free installation, application limits, possibly media, energy connections) and reasonably foreseeable misuse

II. Limitations of the machine

The valve manufacturer sets the limitations for the machine. This concerns e.g. space limitations as well as limitations of use. The space limitations also comprise the interfaces between the valve and the system in which it is to be installed. The manufacturer stipulates the intended use and informs the user about this in the operating instructions and in the sales documents.

System elements to the interface between valves and system (e.g. media lines such as pipelines or conduits, auxiliary media or auxiliary energy connections for the actuator) do not form part of a valve and its actuator and are therefore not mentioned in this document or only mentioned in passing for information purposes.

System controls which serve the technical process or safety purposes, into which the valve is integrated and which request actuation movements from the valve do not form part of the machine.

III. Risks and measures for prevention or reduction

To prevent or sufficiently reduce any risks caused by machines, state-of-the-art safety measures have to be taken, addressing the risks determined through the risk assessment and the health and safety requirements determined in line with Appendix I of the Machinery Directive. Information in the operating instructions about residual risks is only possible and permitted once the manufacturer has exhausted all options for taking protective, state-of-the-art technical measures. This has to take into account the intended use and any reasonably foreseeable misuse. Safety measures should reasonably also be subject to a consideration balancing the effort and the potentially achievable level of safety. With regard to the application, however, they should at least reflect the state of the art.

In the framework of a risk assessment, which is part of the conformity assessment procedure carried out by the manufacturer, the manufacturer has to determine all hazards posed by his machine during all phases of its life cycle. The phases of the life cycle include all tasks carried out by the user of the machine, e.g. installation, commissioning, setup, automatic operation, error recovery, maintenance and certain repairs. In a subsequent step, the manufacturer determines the risks regarding the probability and severity of any hazard determined in the first step. Based on the determined risk, the manufacturer stipulates protective measures according which meet the current state of the art and sufficiently minimise or eliminate the determined risk in each case. The risk assessment becomes part of the technical documents in line with Appendix VII A of the Machinery Directive. These documents remain with the manufacturer who can use them to prove the conformity of the machine with the requirements of the Machinery Directive.

Note: A list of hazards which may be posed by machines can be found in Appendix B1/B2 of EN ISO 12100: 2010.

The following table (table 1) contains a non-comprehensive list of the health and safety requirements from Appendix I of the Machinery Directive. Applicability has to be verified for each section and the measures have to be described.

Note: Valves within the scope of this document are generally installed in systems which may only be operated by trained personnel. From that point of view, measures for these valves are more strongly subject to the question of proportionality than valves which are operated in spaces with public access. For example, certain protective devices which may be required on a valve in a public space may not be required in a non-public space according to the risk assessment.

The following table (table 1) examines health and safety requirements which concern the actuated machine itself and were determined in line with the intended use. For further risks caused by operation (e.g. media-related risks), the required safety measures are usually the responsibility of the user (or e.g. the line builder). On customer request this can also be taken on by the manufacturer.

Table 1: Health and safety requirements in line with Appendix I of the Machinery Directive

Section MD Appendix I	Designation (health and safety requirements)	Relevance	Measures
1.1.	General information		
1.1.1	Terms and definitions	Terms apply to the entire conformity assessment procedure.	No direct measure derived.
1.1.2	Principle	Principles apply to the entire conformity assessment procedure.	No direct measure derived.
1.1.3	Materials and products	Yes. Material faults as far as they have not already been considered in line with the PED.	Design and quality assurance
1.1.4	Lighting	No.	not applicable (n.a.)
1.1.5	Design	Yes. Safe handling and safe transport (note: Other risks which are caused by the design are listed separately elsewhere, if necessary).	A safe transport installation has to be available.
1.1.6	Ergonomics	Yes.	e.g. easy maintenance
1.1.7	Operating positions	No.	n. a.
1.1.8	Seats	No.	n. a.

1.2	Controls and command installations		
1.2.1	Safety and reliability of controls	No for the manufacturer (Yes for the user, e.g. unintentional startup)	Protection against unintentional startup is to be observed by the user
1.2.2	Controls	Yes. e.g. relevant for missing system control	Specific solutions
1.2.3	Startup	Fulfilled if potential hazards are stated in 1.3.	
1.2.4	Decommissioning	No, possibly only for walk-in valves.	
1.2.5	Selecting control or operating modes	No (system control).	
1.2.6	Fault in energy supply	Relevant to order specification. Fulfilled if potential hazards are stated in 1.3.	

1.3.	Protective measures against mechanical hazards		
1.3.1	Stability	Yes. For disassembly and transport. Fixing in the pipeline fulfils the requirement in case of intended use.	Instructions for installation, disassembly and transport (e.g. load points and centres of gravity); also see 1.1.5
1.3.2	Risk of breaking during operation	Yes. Overload of machine or machine parts caused by: a) excessive forces or moments b) ageing/fatigue c) wear d) corrosion e) thermal influence b) – e) only if not already assessed through PEG	a) – e) design and inspection in line with manufacturer or customer specification (also see technical documentation in line with MD Appendix VII A).
1.3.3	Risks from falling or ejected objects	No.	n. a.
1.3.4	Risks from surfaces, edges and corners	Yes.	Design, rounded corners.
1.3.5	Risks from multiple combined machines	No.	n. a.
1.3.6	Risks from change in usage conditions	No.	n. a.

1.3.7	Risks from moving parts	<p>Yes.</p> <p>a) lifting movements (pinching/crushing)</p> <p>b) swivelling movements (e.g. 90°) (pinching/crushing)</p> <p>c) rotation (risk of drawing in)</p>	<p>Based on practical experience, no measures are required for:</p> <p>a) Actuation speeds below 10 mm/s.</p> <p>b) Space between shaft and console constant and low speed (90°/3 s), therefore no hazard.</p> <p>Individual cases have to be examined in case of special designs (e.g. actuation cylinder with lever)</p> <p>c) Free rotation is subject to individual examination.</p> <p>Outside the stated limits, measures (e.g. touch protection) have to be verified.</p>
1.3.8	Selection of protective devices against hazards from moving parts	see 1.3.7	see 1.3.7
1.3.9	Risk of uncontrolled movements	Yes (during the phases installation, disassembly, maintenance, transport).	<p>Ensure prerequisites for proper maintenance and repair.</p> <p>E.g. provide blocking devices (especially during installation and disassembly of actuators).</p>
1.4	Requirements for protective devices		

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1.4.1	General requirements	Yes, in exceptional cases.	see 1.3.7
1.4.2	Special requirements for separating protective equipment	Yes, in exceptional cases.	see 1.3.7
1.4.3	Special requirements for non-separating protective equipment	Yes, in exceptional cases.	see 1.3.7

1.5	Risks from other hazards		
1.5.1	Electrical hazard	Yes, only for voltages over 50 V.	The protection targets of the Low Voltage Directive have to be taken into account for voltages over 50 and 1,000 V (AC) or 75 and 1,500 V (DC).
1.5.2	Static electricity	Yes (e.g. for housings with plastic lining).	Create preconditions (e.g. for earthing).
1.5.3	Non-electric energy supply	Yes. Pneumatics/hydraulics. User-supplied medium (e.g. nitrogen, natural gas). Valves controlled with own medium.	Safe handling of stored energy (e.g. spring release). Provide additional information on preventing leaks in the operating instructions for the user.
1.5.4	Assembly/installation error	Yes. Note: Assembly at the manufacturing plant has to be differentiated from installation of the valve at the user's site or re-assembly at the user's site: a) assembly at the manufacturer b) e.g. connection to wrong actuator, incorrect installation with regard to direction of flow, installation of wear parts, etc.	a) internal QA measures b) installation and assembly in line with manufacturer's specifications in the operating instructions or in separate assembly instructions, if applicable.

1.5.5	Extreme temperatures	Distinguishing cases: a) heat generation of the valve (e.g. in case of continuously charged magnetic actuators) b) heat or cold generated due to media	to a) e.g. separating protective device, such as insulation to b) operating elements have to be designed accordingly Operating instructions: information about further protective measures through media temperature
1.5.6	Fire	No.	
1.5.7	Explosion	Yes.	Valves which are to be operated in a potentially explosive atmosphere fall under the scope of ATEX.
1.5.8	Noise	Distinguishing cases: a) noise caused by media or processes is outside the scope of the MD b) noise caused by the valve (e.g. venting processes on pneumatic actuators)	to b) e.g. attenuators
1.5.9	Vibration	No.	
1.5.10	Radiation	No.	
1.5.11	Radiation from outside	Yes.	Apply EMC directive.
1.5.12	Laser radiation	No.	

1.5.13	Emission of hazardous materials and substances	Yes, if pressure below or at 0.5 bar	Prevention (e.g. use of suitable sealing systems)
1.5.14	Risk of being locked inside a machine	Not relevant.	
1.5.15	Slipping, tripping and falling hazard	Possibly yes. Check whether relevant (e.g. valve as step).	If necessary, add information in the operating instructions.
1.5.16	Lightning	Not relevant. Note: Issue can be relevant to the user.	

IV. Documentation

The relevance of the Machinery Directive may change or supplement the previous documentation (e.g. in line with the Pressure Equipment Directive) in line with the following table (table 2) in the sections described there.

Note: The technical documents (according to Appendix VII A MD) or the special technical documents (according to Appendix VII B MD) have to be created by the manufacturer and submitted to the relevant authorities on request.

Table 2: Documentation

Valve configuration	Documentation	Machine type acc. to MD N = no machine P = partially completed machine C = completed machine
Valve with manual actuator	No documentation requirement by MD (i.e. documentation, e.g. in line with PED)	N

<p>a) valve manufacturer supplies actuator (assembled or not assembled).</p> <p>b) valve without actuator, but with clearly defined actuator (type, interfaces, performance and connecting elements, and precise installation information for the actuator system)</p> <p>Note: The type describes the actuator defined in the operating instructions by the valve manufacturer (i.e. the inherent actuator and other actuators which have similar security properties).</p>	<p><u>Valve manufacturer:</u> Also to be supplied:</p> <ul style="list-style-type: none"> • CE marking • EU Declaration of Conformity in line with the applied directives (one document) • Operating instructions PED/MD/possibly others • The required interface description of valve and actuator • Risk assessment of the possible hazards arising from the valve incl. actuator in line with the intended use (see table 1). <p>Not required:</p> <ul style="list-style-type: none"> • Technical documents according to Appendix VII A (e.g. risk assessment) <p><u>User:</u> The user must comply with the specifications from the technical documentation incl. the operating instructions, particularly in terms of choosing the actuator.</p> <p>In case b), the user confirms that a professional installation has taken place and adds this declaration to the documentation. The automation is the user's responsibility.</p>	<p>C</p>
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<p>Valve without actuator, with interface to automation, but not intended for a clearly defined actuator system</p>	<p>Also to be supplied:</p> <ul style="list-style-type: none"> • Installation declaration • Installation instructions (see MD Appendix VI) • CE marking if applicable, EU Declaration of Conformity (according to other directives, such as DGRL, ATEX-RL), operating instructions (all, if applicable) <p>Not required:</p> <ul style="list-style-type: none"> • Special technical documents according to Appendix VII B (e.g. risk assessment) 	<p>P</p>
<p>Valve actuator</p>	<p>Also to be supplied:</p> <ul style="list-style-type: none"> • Installation declaration • Installation instructions (see MD Appendix VI) • CE marking (if applicable, e.g. according to EMC), EU Declaration of Conformity (according to other directives) and operating instructions <p>Not required:</p> <ul style="list-style-type: none"> • Special technical documents according to Appendix VII B (e.g. risk assessment) 	<p>P</p>

V. Further reading

- EN ISO 12100 Safety of machinery – General principles of design – Risk assessment and risk reduction
- EN ISO 13854 Safety of machinery – Minimum gaps to avoid crushing of parts of the human body (not yet harmonised with the MD)
- EN 60204-1 Safety of machinery – Electrical equipment of machines – Part 1: General requirements
- EN ISO 4413 Fluid technology – General rules and safety requirements on hydraulic systems and their components
- EN ISO 4414 Fluid technology – General rules and safety requirements on pneumatic systems and their components
- Namur recommendation NE 14 Attachment of Pneumatic Part-Turn Actuators to Valves
- EN 15081 Industrial valves – Mounting kits for part-turn valve actuator attachment