

Contents		Page
European foreword		5
Introduction.....		6
1 Scope.....		7
2 Normative references		7
3 Terms and definitions.....		7
3.1 Terms relating to the AI Act		7
3.2 Terms related to the risk management system		10
3.3 Terms relating to testing.....		12
3.4 Terms related to the AI system		13
3.5 Terms related to natural persons		14
3.6 Terms related to the risk management process.....		16
4 Requirements for the <i>risk management system</i>		19
4.1 <i>Risk management process</i>		19
4.2 Management responsibilities		21
4.2.1 <i>Risk management process</i> implementation and review.....		21
4.2.2 <i>Risk management policy</i> for establishing the <i>risk acceptability criteria</i>		22
4.3 Competence of personnel		22
4.4 <i>Risk acceptability criteria</i>		23
4.4.1 General requirements for <i>risk acceptability criteria</i>		23
4.4.2 <i>Process</i> for establishing and updating <i>risk acceptability criteria</i> for <i>residual risk</i>		24
4.4.3 <i>Process</i> for establishing <i>risk acceptability criteria</i> for the overall <i>residual risk</i>		26
4.5 <i>Risk management plan</i>		27
4.6 <i>Risk management file</i>		27
5 Risk management process and AI system life cycle		28
6 Risk analysis		31
6.1 General.....		31
6.2 <i>Risk identification</i>		32
6.2.1 <i>Intended purpose</i>		32
6.2.2 <i>Reasonably foreseeable misuse</i>		33
6.2.3 Identification of the <i>AI system's</i> characteristics related to <i>risks</i>		33
6.2.4 Identification of <i>hazards, risk scenarios</i> and <i>hazardous situations</i>		34
6.3 Risk estimation		37
7 <i>Risk evaluation</i>		39
8 <i>Testing</i>		40
8.1 General.....		40
8.2 <i>Test plan</i>		41
8.3 <i>Real-world conditions testing</i>		42
8.4 Test monitoring and test reporting.....		43
9 <i>Risk control</i>		43
9.1 Hierarchy of <i>risk control</i>		43
9.1.1 General.....		43
9.1.2 Applying the hierarchy of <i>risk control</i>		44
9.2 Implementation and <i>verification of risk control measures</i>		46
9.3 <i>Residual risk evaluation</i>		47

9.4	Completeness of <i>risk control</i>	47
10	Evaluation of overall <i>residual risk</i>	47
11	<i>Risk management</i> review.....	48
12	<i>Pre-market</i> and <i>post-market</i> activities.....	49
12.1	General.....	49
12.2	Information collection.....	49
12.3	Information review.....	50
12.4	Actions to take.....	50
Annex A (informative) Examples of <i>hazards</i> and related <i>risk</i> scenarios, <i>hazardous situations</i> and <i>harms</i>		52
Annex B (informative) <i>Risk management process</i> and concepts overview.....		56
B.1	<i>Risk management process</i>	56
B.2	Relationship between <i>hazard</i> , <i>risk</i> scenario, <i>hazardous situation</i> and <i>harm</i>	58
Annex C (informative) <i>Fundamental rights</i> considerations.....		59
C.1	General.....	59
C.2	Variation in <i>fundamental rights</i> protection.....	59
C.2.1	General.....	59
C.2.2	Who bears legal obligations to respect <i>fundamental rights</i> ?.....	59
C.2.3	What is the scope, strength and character for protecting a fundamental right?.....	60
C.2.3.1	Scope.....	60
C.2.3.2	Strength.....	60
C.2.3.3	The character of the right.....	60
C.3	Establishing <i>risk</i> acceptability criteria for <i>fundamental rights</i> interferences.....	61
C.3.1	General.....	61
C.3.2	Assessing the extent of an <i>interference</i> with <i>fundamental rights</i>	61
Annex D (informative) <i>Objective evidence</i> in relation to the establishment of <i>risk</i> acceptability criteria.....		64
Annex E (informative) ISO 31000.....		65
Annex ZA (informative) Relationship between this European Standard and the essential requirements of aimed to be covered essential requirements of Regulation 2024/1689 aimed to be covered.....		66
Bibliography.....		67
Figures		
Figure 1 — A schematic representation of the <i>risk management process</i>		21
Figure 2 — Illustration of the relationship between the <i>AI system life cycle</i> stages and the <i>risk management process</i>		30
Figure B.1 — <i>Risk management process</i> diagram for <i>AI systems</i> with references to clauses.....		57
Figure B.2 — Illustration of the relationship between <i>hazard</i> , <i>risk</i> scenario, <i>hazardous situation</i> and <i>harm</i>		58
Tables		
Table A.1 — Relationship between <i>hazards</i> , <i>risk</i> scenarios, <i>hazardous situations</i> and the <i>harm</i> that can occur.....		52
Table ZA.1 — Correspondence between this European Standard and Regulation 2024/1689.....		66