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Article 001

Specification Subject matter

Relationship with Standard 24029-1-Assessment of L..., 22989-Artificial inte..., 24030-Use cases..., 38507-Governance impl..., 24028-Overview of tru... (Artificial Intelligence); 25010-SQuaRE - Produc..., 14971-Application of..., 5469-TR Functional s..., 24368-Overview of eth..., 24028-Overview of tru... (Safety)

Link <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689>

Summary The purpose of this Regulation is to improve the functioning of the internal market and promote the uptake of human-centric and trustworthy AI, while ensuring a high level of protection of health, safety, fundamental rights, including democracy, the rule of law and environmental protection, support innovation

Full text Subject matter*
1. The purpose of this Regulation is to improve the functioning of the internal market and promote the uptake of human-centric and trustworthy artificial intelligence (AI), while ensuring a high level of protection of health, safety, fundamental rights

Terms	Variant	Complementary	Standard	
216 Human-centric				22
96 Trustworthy				22
194 Artificial intelligence		24029-1, 22989, 24030, 38507, 24028		22
212 Health				22
214 Safety		25010, 14971, 5469, 24368, 24028		22
209 Fundamental rights				22
217 Democracy				22
218 Environmental protection				22
220 Harmful effects				22
219 Innovation				22

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Observations

Article 002

Specification Scope

Relationship with Standard 25059-Quality model f..., 5338-AI System life ..., 24030-Use cases..., 24028-Overview of tru..., 6254-Objective and a..., 17847-Verification an..., 22443-Guidance on add... (AI systems); 12182-Framework for c... (Service)

Link <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689>

Summary The Regulation applies to:
- providers
- deployers
- located in the Union
- located in a third country with output used in the Union
- Importers

Full text Scope
1. This Regulation applies to:
(a) providers placing on the market or putting into service AI systems or placing on the market general-purpose AI models in the Union, irrespective of whether those providers are established or located within the

Terms	Variant	Complementary	Standard	
222 Providers				23
223 Deployers				23
225 Located in the Union				23
224 Located in a third country with output used				23
226 Importers				23
227 Product manufacturers				23
228 Location				23
229 Products covered by Union harmonization				23
4 AI systems		25059, 5338, 24030, 24028, 6254, 17847, 22443		23
255 Service		12182		23

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Observations

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Article 003

Specification Definitions

Relationship with Standard
25059-Quality model f..., 5338-AI System life ..., 24030-Use cases..., 24028-Overview of tru..., 6254-Objective and a..., 17847-Verification an..., 22443-Guidance on add..., (AI systems); 27000-Information sec..., (Conformity); 24029-1-Assessment of t..., 22989-Artificial inte..., 24030-Use cases..., 38507-Governance impl..., 24028-Overview of tru..., (Artificial intelligence); 9868-Biometric ident..., (Biometric data)

Link <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689>

Summary The article start with a definition of Artificial Intelligence system continuing with mentioning other terms such as: risk, AI model, deployer, authorized representative, importer, distributor, operator, placing on the market, making available on the market, putting into service, intended purpose, reasonable foreseeable misuse, safety

Full text **Definitions**
For the purposes of this Regulation, the following definitions apply:
(1) 'AI system' means a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and

Terms	Variant	Complementary	Standard
194 Artificial intelligence			24029-1, 22989, 24030, 38507, 24028
4 AI systems			25059, 5338, 24030, 24028, 6254, 17847, 22443
223 Deployers			
226 Importers			
144 Conformity			27000
290 Biometric data			9868

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Observations

Article 004

Specification AI literacy

Relationship with Standard
25059-Quality model f..., 5338-AI System life ..., 24030-Use cases..., 24028-Overview of tru..., 6254-Objective and a..., 17847-Verification an..., 22443-Guidance on add..., (AI systems); 25019-Quality-in-use..., (Experience); 22989-Artificial inte..., (Knowledge); 24028-Overview of tru..., (Training)

Link <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689>

Summary Providers and deployers ensure the AI literacy to their staff

Full text **AI literacy**
Providers and deployers of AI systems shall take measures to ensure, to their best extent, a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge,

Terms	Variant	Complementary	Standard
222 Providers			
223 Deployers			
234 Literacy			
231 Knowledge			22989
134 Experience			25019
232 Education			
233 Training			24028
4 AI systems			25059, 5338, 24030, 24028, 6254, 17847, 22443
230 AI literacy			

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Observations

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Article 005

Specification Prohibited AI Practices

Relationship with Standard 25024-Measurement of ..., 5259-2-Data quality me..., 25059-Quality model f..., 25019-Quality-in-use ..., 25012-Data quality mo..., (Accessibility); 14971-Application of ... (Market for medical or safety reasons); 9868-Biometric ident... (Biometric data)

Link <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689>

Summary The following AI practices shall be prohibited:
 - manipulative or deceptive techniques
 - the placing on the market the use of an AI system that exploit any vulnerabilities of a person or a specific group of persons due to their age, disability or a specific social or economic situation - evaluation or classification of natural persons or

Full text **Prohibited AI practices**
 1. The following AI practices shall be prohibited:
 (a) the placing on the market, the putting into service or the use of an AI system that deploys subliminal techniques beyond a person's consciousness or purposefully manipulative or deceptive techniques, with

Terms	Variant	Complementary	Standard
239	Market for medical or safety reasons		14971
1	Accessibility		25024, 5259-2, 25059, 25019, 25012
290	Biometric data		9868
288	Disability		
83	Aggregation		

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Observations

Article 006

Specification Classification rules for high-risk AI systems

Relationship with Standard 25059-Quality model f..., 5338-AI System life ..., 24030-Use cases..., 24028-Overview of tru..., 6254-Objective and a..., 17847-Verification an..., 22443-Guidance on add... (AI systems); 42001-Management syst..., 5259-3-Data quality ma..., 23894-Guidance on ris..., 27000-Information sec..., 24970-AI system logg..., 31000-Guidelines..., 25058-Guidance for qu... (Risk management); 25010-SQualRE - Produc..., 14971-Application of ..., 5469-TR Functional s..., 24368-Overview of eth..., 24028-Overview of tru... (Safety); 23894-Guidance on ris... (Products); 4213-Assessment of M... (Classification); 12182-Framework for c... (Service); 38507-Governance impl... (Decision-making)

Link <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689>

Summary The document distinguishes for AI systems the level of risks

Full text **Classification rules for high-risk AI systems**
 1. Irrespective of whether an AI system is placed on the market or put into service independently of the products referred to in points (a) and (b), that AI system shall be considered to be high-risk where both of the following conditions are fulfilled:

Terms	Variant	Complementary	Standard
253	Classification		4213
4	AI systems		25059, 5338, 24030, 24028, 6254, 17847, 22443
255	Service		12182
236	Products		23894
212	Health		
214	Safety		25010, 14971, 5469, 24368, 24028
209	Fundamental rights		
256	Decision-making		38507
101	Risk management		42001, 5259-3, 23894, 27000, 24970, 31000, 25058

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Observations

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Article 007

Specification Amendment, to Annex III

Relationship with Standard [25059](#)-Quality model f..., [5338](#)-AI System life ..., [24030](#)-Use cases..., [24028](#)-Overview of tru..., [6254](#)-Objective and a..., [17847](#)-Verification an..., [22443](#)-Guidance on add... (AI systems); [42001](#)-Management syst..., [5259-3](#)-Data quality ma..., [23894](#)-Guidance on ris..., [27000](#)-Information sec..., [24970](#)-AI system loggi..., [31000](#)-Guidelines..., [25058](#)-Guidance for qu... (Risk management); [25010](#)-SQualRE - Produc..., [14971](#)-Application of ..., [5469](#)-TR Functional s..., [24368](#)-Overview of eth..., [24028](#)-Overview of tru... (Safety); [24030](#)-Use cases... (Use-cases); [24028](#)-Overview of tru..., [8200](#)-Controllability..., [29119-11](#)-Guidelines on t... (Autonomy)

Link <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689>

Summary Amendmenys to Annex III by adding or modifying use-cases of high-risks, regarding AI systems

Full text Amendments to Annex III
 1. The Commission is empowered to adopt delegated acts in accordance with Article 97 to amend Annex III by adding or modifying use-cases of high-risk AI systems where both of the following conditions are fulfilled:

Terms	Variant	Complementary	Standard
258 Use-cases			24030 30
4 AI systems			25059 , 5338 , 24030 , 24028 , 6254 , 17847 , 22443 30
212 Health			30
214 Safety			25010 , 14971 , 5469 , 24368 , 24028 30
209 Fundamental rights			30
101 Risk management			42001 , 5259-3 , 23894 , 27000 , 24970 , 31000 , 25058 30
266 Autonomy			24028 , 8200 , 29119-11 30

OPTIONAL INFORMATION

Name and Surname Affiliation and Qualification LinkedIn ... other

Observations

Article 008

Specification Compliance with the requirements

Relationship with Standard [27000](#)-Information sec... (Compliance with the requirements)

Link <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689>

Summary High-risk AI systems shall comply with the requirements laid down in the Section 2. The risk managemnt system referred to in Article 9 shall be considered when ensuring compliance with those requirements.

Full text Compliance with the requirements
 1. High-risk AI systems shall comply with the requirements laid down in this Section, taking into account their intended purpose as well as the generally acknowledged state of the art on AI and AI-related technologies. The risk management system referred to

Terms	Variant	Complementary	Standard
147 Compliance with the requirements			27000 20

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	Terms	Variant	Complementary	Standard	
Article 009	101 Risk management		42001, 5259-3, 23894, 27000, 24970, 31000, 25058		19
Specification	49 Lifecycle		24027, 5338, 17847, 22443, 5339, 62304		19
Relationship with Standard	145 Documented information		27000		19
24027-Bias in AI syst.... 5338-AI System life 17847-Verification an.... 22443-Guidance on add.... 5339-Guidance for AI.... 62304-Software life c... (Lifecycle); 42001-Management syst.... 5259-3-Data quality ma.... 23894-Guidance on ris.... 27000-Information sec.... 24970-AI system loggi.... 31000-Guidelines.... 25058-Guidance for qu... (Risk management); 27000-Information sec... (Documented information); 5259-1-Overview, termi.... 27000-Information sec... (Measurement); 27000-Information sec.... 14971-Application of ... (Residual risk); 27000-Information sec.... 14971-Application of ... (Risk evaluation)	158 Risk evaluation		27000, 14971		19
Link	154 Residual risk		27000, 14971		19
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689	153 Measurement		5259-1, 27000		19
Summary					
A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI system.					
Full text	OPTIONAL INFORMATION				
Risk management system	Name and Surname	Domenico Natale	Affiliation and UNI CT 533 (member) Qualification UNI CT 504 (president)	LinkedIn https://www.linkedin.com/in/domenico-natale-a9b99812/?... other originalSubdomain=it	
1. A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems.	Observations				
2. The risk management system shall be understood as a continuous iterative process planned and run					

	Terms	Variant	Complementary	Standard	
Article 010	74 Training, validation, testing datasets		25024, 5259-2, 24029-1		10
Specification	57 Quality criteria		25024, 5259-2		10
Relationship with Standard	52 Origin of data	provenance	5259-2		10
25059-Quality model f... (Annotation); 5259-2-Data quality me... (Bias detection and correction); 25012-Data quality me... (Complete); 25024-Measurement of ... 5259-2-Data quality me... 25012-Data quality mo.... 24028-Overview of tr... (Consistency); 5259-1-Overview, termi.... 31010-Risk assessment... (Data collection processes); 24027-Bias in AI syst.... 23894-Guidance on ris.... 82079-1-IEC Part 1: pri.... 26514-Design and deve... (Design); 5259-2-Data quality me... (Origin of data); 25024-Measurement of ... 5259-2-Data quality me... (Quality criteria); 25024-Measurement of ... 5259-2-Data quality me.... 24029-1-Assessment of t... (Training, validation, testing datasets); 42001-Management syst... (Cleaning); 8183-Data life cycle ... 5259-5-Data quality go.... 38500-Governance of l... 38507-Governance impl... (Governance); 5259-1-Overview, termi.... 25019-Quality-in-use 25012-Data quality mo.... 8000-1-Overview... (Data quality)	13 Bias detection and correction		5259-2		10
Link	53 Personal data are not to be transmitted,				10
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689	111 Governance		8183, 5259-5, 38500, 38507		10
Summary	34 Design		24027, 23894, 82079-1, 26514		10
High-risk AI systems shall be developed on the basis of training, validation and testing data sets that meet the quality criteris referred to in paragraphs 2 to 5.	46 HR AI Systems				10
Full text	29 Data collection processes		5259-1, 31010		10
Data and data governance	5 Annotation		25059		10
1. High-risk AI systems which make use of techniques involving the training of AI models with data shall be developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5 whenever such data sets are used.	25 Consistency		25024, 5259-2, 25012, 24028		10
	80 Cleaning		42001		10
	102 Labelling				10
	116 Data quality		5259-1, 25019, 25012, 8000-1		10
	19 Complete		25012		10
	83 Aggregation				10
	33 Data-preparation processing				10
	82 Enrichment				10
	42 Formulation of assumptions (information)				10
	44 Fundamental rights or lead to discrimination				10
	OPTIONAL INFORMATION				
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	Observations				

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Article 011

Specification
 Technical documentation

Relationship with Standard
 27000-Information sec... (Documented information); 82079-1-IEC Part 1: pri... (Technical documentation)

Link
<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689>

Summary
 Technical documentation of a high-risk shall be drawn before that the system is on the market or put into service and shall be kept up-to date

Full text
 Technical documentation
 1. The technical documentation of a high-risk AI system shall be drawn up before that system is placed on the market or put into service and shall be kept up-to date.
 The technical documentation shall be drawn up in such

Terms	Variant	Complementary	Standard
145 Documented information			27000 28
246 Technical documentation			82079-1 28

OPTIONAL INFORMATION

Name and Surname Affiliation and UNI Qualification LinkedIn ... other

Observations

Article 012

Specification
 Record keeping

Relationship with Standard
 25024-Measurement of ...; 5259-2-Data quality me...; 24970-AI system loggi...; 25012-Data quality mo... (Traceability); 42001-Management syst...; 5259-3-Data quality ma...; 23894-Guidance on ris...; 27000-Information sec...; 24970-AI system loggi...; 31000-Guidelines...; 25058-Guidance for qu... (Risk management); 24970-AI system loggi... (Logging)

Link
<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689>

Summary
 Logging capabilities in order to ensure a level of traceability and functioning of High-risk

Full text
 Record-keeping
 1. High-risk AI systems shall technically allow for the automatic recording of events (logs) over the lifetime of the system.
 2. In order to ensure a level of traceability of the functioning of a high-risk AI system that is appropriate

Terms	Variant	Complementary	Standard
245 Logging			24970 27
73 Traceability			25024, 5259-2, 24970, 25012 27
101 Risk management			42001, 5259-3, 23894, 27000, 24970, 31000, 25058 27

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Observations

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Article 014

Specification: Human oversight

Relationship with Standard: 25059-Quality model f..., 5338-AI System life ..., 24030-Use cases..., 24028-Overview of tru..., 6254-Objective and a..., 17847-Verification an..., 22443-Guidance on add... (AI systems); 25010-SQuaRE - Produc..., 14971-Application of ..., 5469-TR Functional s..., 24368-Overview of eth..., 24028-Overview of tru... (Safety); 8200-Controllability... (Controller)

Link: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689>

Summary: High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which they are in use. Human oversight shall aim to prevent or minimise the risks to health, safety or fundamental rights

Full text: Human oversight
1. High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which they are in use.

Terms	Variant	Complementary	Standard	
114	Context of use			33
4	AI systems	25059, 5338, 24030, 24028, 6254, 17847, 22443		33
212	Health			33
214	Safety	25010, 14971, 5469, 24368, 24028		33
278	Controller	8200		33

OPTIONAL INFORMATION

Name and Surname:

Affiliation and Qualification:

Linkedin ... other:

Observations:

Article 015

Specification: Accuracy, robustness and cybersecurity

Relationship with Standard: 25024-Measurement of ..., 5259-2-Data quality me..., 25012-Data quality mo..., 29119-11-Guidelines on t... (Accuracy); 5259-2-Data quality me... (Bias detection and correction); 24029-1-Assessment of t..., 24029-2-Assessment of t... (Robustness); 5259-2-Data quality me..., 22989-Artificial inte... (Data quality reporting); 5259-1-Overview, term..., 31010-Risk assessment... (Data collection processes); 24027-Bias in AI syst..., 5338-AI System life ..., 17847-Verification an..., 22443-Guidance on add..., 5339-Guidance for AI..., 62304-Software life c... (Lifecycle); 25024-Measurement of ..., 42001-Management syst..., 27000-Information sec... (Measurement and method); 5259-2-Data quality me... (Origin of data); 25059-Quality model f..., 25010-SQuaRE - Produc..., 24028-Overview of tru..., 9868-Biometric ident... (Security); 22989-Artificial inte... (Cybersecurity)

Link: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689>

Summary: High-risk AI systems shall be designed and developed in such a way that they achieve an appropriate level of accuracy robustness and cybersecurity...throughout their lifecycle.

Full text: Accuracy, robustness and cybersecurity
1. High-risk AI systems shall be designed and developed in such a way that they achieve an appropriate level of accuracy, robustness, and cybersecurity, and that they perform consistently in those respects throughout their lifecycle.

Terms	Variant	Complementary	Standard	
47	Interaction with natural person or other			15
2	Accuracy	25024, 5259-2, 25012, 29119-11		15
65	Robustness achieved with redundancy,			15
29	Data collection processes	5259-1, 31010		15
50	Measurement and method	25024, 42001, 27000		15
46	HR AI Systems			15
13	Bias detection and correction	5259-2		15
49	Lifecycle	24027, 5338, 17847, 22443, 5339, 62304		15
48	Level declaration & instruction of use			15
66	Security	25059, 25010, 24028, 9868		15
41	Examination of biases, health and safety of			15
52	Origin of data	5259-2		15
67	Security and privacy, pseudonymisation			15
28	Data quality reporting	5259-2, 22989		15
50	Measurement and method	25024, 42001, 27000		15
18	Robustness	24029-1, 24029-2		15
215	Cybersecurity	22989		15
45	How to measure, metrology			15

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Article 017

Specification Quality management system

Relationship with Standard 25024-Measurement of ..., 5259-2-Data quality me..., 25059-Quality model f..., 25019-Quality-in-use ..., 25012-Data quality mo..., (Accessibility); 25059-Quality model f..., (AI models); 5259-2-Data quality me... (Bias detection and correction); 25024-Measurement of ..., 5259-2-Data quality me..., 25019-Quality-in-use ..., 25012-Data quality mo... (Compliance); 5259-2-Data quality me... (Data holder); 5259-2-Data quality me... (Identifiability); 8183-Data life cycle..., 5259-1-Overview, termi..., 5259-4-Data quality pr..., (Data life cycle); 24027-Bias in AI syst..., 23894-Guidance on ris..., 82079-1-IEC Part 1: pri..., 26514-Design and deve... (Design); 24027-Bias in AI syst..., 5338-AI System life ..., 17847-Verification an..., 22443-Guidance on add..., 5339-Guidance for AI..., 62304-Software life c..., (Lifecycle); 42001-Management syst... (Cleaning); 42001-Management syst..., 23894-Guidance on ris... (Leadership); 42001-Management syst... (Planning); 25019-Quality-in-use ... (Post-market); 42001-Management syst..., 5259-3-Data quality ma..., 23894-Guidance on ris..., 27000-Information sec..., 24970-AI system logg..., 31000-Guidelines..., 25058-Guidance for qu... (Risk management); 42001-Management syst..., 5339-Guidance for AI... (Accountability)

Link <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689>

Summary Providers of high-risk AI systems shall put a quality management system in place that ensures compliance with the AI Act regulation.

Full text **Quality management system**
 1. Providers of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions, and shall

Terms	Variant	Complementary	Standard	
22	Data holder		5259-2	17
86	Leadership		42001, 23894	17
49	Lifecycle		24027, 5338, 17847, 22443, 5339, 62304	17
58	Re-use of the personal data	Quality control		17
71	The personal data in the special categories			17
84	Assessment datasets			17
30	Data life cycle		8183, 5259-1, 5259-4	17
3	AI models		25059	17
80	Cleaning		42001	17
87	Planning		42001	17
21	Compliance		25024, 5259-2, 25019, 25012	17
24	Identifiability		5259-2	17
34	Design		24027, 23894, 82079-1, 26514	17
100	Post-market	Quaiy in use	25019	17
1	Accessibility		25024, 5259-2, 25059, 25019, 25012	17
101	Risk management		42001, 5259-3, 23894, 27000, 24970, 31000, 25058	17
13	Bias detection and correction		5259-2	17
273	Accountability		42001, 5339	17

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Observations

Article 043

Specification Conformity assessment

Relationship with Standard 25059-Quality model f..., 5338-AI System life ..., 24030-Use cases..., 24028-Overview of tru..., 6254-Objective and a..., 17847-Verification an..., 22443-Guidance on add..., (AI systems); 27000-Information sec... (Conformity); 5259-3-Data quality ma..., 14971-Application of ..., 38500-Governance of l..., 9868-Biometric ident... (Management); 25010-SQuaRE - Produc..., 14971-Application of ..., 5469-TR Functional s..., 24368-Overview of eth..., 24028-Overview of tru... (Safety); 82079-1-IEC Part 1: pri... (Technical documentation); 29119-11-Guidelines on L... (Assessment)

Link <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689>

Summary Conformity assessment procedures are based on:
- the internal control referred to in Annex VI
- the assessment of the quality management system and the technical documentation

Full text **Conformity assessment**
 1. For high-risk AI systems listed in point 1 of Annex III, where, in demonstrating the compliance of a high-risk AI system with the requirements set out in Section 2, the provider has applied harmonised standards referred to in Article 40, or, where applicable,

Terms	Variant	Complementary	Standard	
170	Management		5259-3, 14971, 38500, 9868	32
289	Quality management			32
246	Technical documentation		82079-1	32
144	Conformity		27000	32
286	Assessment		29119-11	32
212	Health			32
214	Safety		25010, 14971, 5469, 24368, 24028	32
4	AI systems		25059, 5338, 24030, 24028, 6254, 17847, 22443	32

OPTIONAL INFORMATION

Name and Surname: | Affiliation and Qualification: | LinkedIn ... other

Observations

