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Article 009				Terms	% Variant	Text	Standard	Terms	Text	Whereas
Relationship with Standard	Risk management system	101	Risk management	42027-2021 ISO/IEC TR-Bias in AI syst...; 5338-2023 ISO/IEC-AI System life ...; 17847 ISO/IEC TS-Verification an...; 22443 ISO/IEC AWI TS-Guidance on add...; 5339-2024 ISO/IEC-Guidance for AI...; 62304-2008 IEC-Medical device ... (Lifecycle); 42001-2023 ISO/IEC-Management syst...; 5259-3-2024 ISO/IEC-Data quality me...; 23894-2023 ISO/IEC-Guidance on ris...; 27000-2018 ISO/IEC-Information sec...; 24970 ISO/IEC AWI-AI system loggi...; 31000-2018 ISO-Risk management...; 25058-2024 ISO/IEC TS-Guidance for qu... (Risk management); 42001-2023 ISO/IEC-Management syst...; 27000-2018 ISO/IEC-Information sec... (Documented information); 42001-2023 ISO/IEC-Management syst...; 5259-1-2024 ISO/IEC-Overview, term...; 27000-2018 ISO/IEC-Information sec...; 25059-1-ISOIEC AWI-Quality model f...; 4213-1 ISO/IEC AWI-Performance mea... (Measurement); 27000-2018 ISO/IEC-Information sec...; 14971-2019 ISO-Application of ... (Residual risk); 27000-2018 ISO/IEC-Information sec...; 14971-2019 ISO-Application of ... (Risk evaluation)	42001-2023 ISO/IEC 5338-3-2024 ISO/IEC_23894-3-2024 ISO/IEC_27000-2018 ISO/IEC AWI_31000-2018 ISO_25058-2024 ISO/IEC TS ISO/IEC AWI TS, 5339-2024 ISO/IEC 62304-2006 IEC	19	( )	19		
	49	Lifecycle	24027-2021 ISO/IEC TR_5338-2023 ISO/IEC_17847 ISO/IEC TS, 22443 ISO/IEC AWI TS, 5339-2024 ISO/IEC 62304-2006 IEC	19						
	145	Documented information	42001-2023 ISO/IEC_27000-2018 ISO/IEC	19						
	158	Risk evaluation	27000-2018 ISO/IEC_14971-2019 ISO	19						
	154	Residual risk	27000-2018 ISO/IEC_14971-2019 ISO	19						
	153	Measurement	42001-2023 ISO/IEC_5259-1-2024 ISO/IEC_27000-2018 ISO/IEC_25059-1 ISO/IEC AWI_4213-1 ISO/IEC AWI	19						
Relationship with Standard	Link <a href="https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689">https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689</a>	Full text	Risk management system	1. A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems. 2. The risk management system shall be understood as a continuous iterative process planned and run throughout the entire lifecycle of a high-risk AI system, requiring regular systematic review and updating. It shall comprise the						
	OPTIONAL INFORMATION				Name and Surname	Domenico Natale	Affiliation and UNI CT 533 (member) Qualification UNI CT 504 (president)	LinkedIn <a href="https://www.linkedin.com/in/domenico-natale-a9b99812/">https://www.linkedin.com/in/domenico-natale-a9b99812/</a> ... other originalSubdomain=it		
	Observations									
Article 010				Terms	% Variant	Text	Standard	Terms	Text	Whereas
Relationship with Standard	Data and data governance	74	Training, validation, testing datasets	25024-2015 ISO/IEC_5259-2-2024 ISO/IEC FDIS_24029-1-2021 ISO/IEC TR	10	( )	10			
	57	Quality criteria	25024-2015 ISO/IEC_5259-2-2024 ISO/IEC FDIS	10						
	52	Origin of data	5259-2-2024 ISO/IEC FDIS	10						
	13	Bias detection and correction	5259-2-2024 ISO/IEC FDIS	10						
	53	Personal data are not to be transmitted, transferred or otherwise accessed by	5259-2-2024 ISO/IEC FDIS	10						
	111	Governance	8183-2023 ISO/IEC_5259-5-2024 ISO/IEC FDIS_38500-2024 ISO/IEC TR, 38507-2022 ISO/IEC	10						
	34	Design	24027-2021 ISO/IEC TR_23894-2023 ISO/IEC_82079-1-2019 IEC/IEEE_26514-2022 ISO/IEC TR-Assessment of t... (Training, validation, testing datasets); 42001-2023 ISO/IEC-Management syst... (Cleaning); 5259-2-2024 ISO/IEC-FDIS-Data quality me... (Datasets); 8183-2023 ISO/IEC-Data life cycle...; 5259-5-2024 ISO/IEC-FDIS-Data quality go...; 38500-2024 ISO/IEC-Governance of l...; 38507-2022 ISO/IEC-Governance impl... (Governance); 42001-2023 ISO/IEC-Management syst...; 5259-1-2024 ISO/IEC-Overview, term...; 25019-2023 ISO/IEC-Quality-in-use...; 25012-2008 ISO/IEC-Data quality me...; 8001-1-2022 ISO-Part 1: Overview...; 5259-6-2024 CD TR-Visualization ... (Data quality); 25024-2015 ISO/IEC-Measurement of ...; 5259-2-2024 ISO/IEC-FDIS-Data quality me...; 42001-2023 ISO/IEC-Management syst...; 24028-2020 ISO/IEC TR-Overview of tru...; 25223-2024 ISO/IEC AWI TS-Guidance and re...; 5259-6-2024 CD TR-Visualization f... (Data)	10						
	46	HR AI Systems	5259-1-2024 ISO/IEC_31010-2019 IEC	10						
	29	Data collection processes	5259-1-2024 ISO/IEC_31010-2019 IEC	10						
	5	Annotation	25059-2023 ISO/IEC	10						
Relationship with Standard	25	Consistency	25024-2015 ISO/IEC_5259-2-2024 ISO/IEC FDIS_25012-2008 ISO/IEC TR, 24028-2020 ISO/IEC TR	10						
	80	Cleaning	42001-2023 ISO/IEC	10						
	Link <a href="https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689">https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689</a>	Full text	Data and data governance	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. 2. Training, validation and testing data sets shall be subject to data governance and management practices						
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	Observations									

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Specification	Relationship with Standard	Article 015				Whereas
		Terms	% Variant	Text	Standard	
		47   Interaction with natural person or other systems				2   Accuracy
		2   Accuracy		25024:2015 ISO/IEC, 5259-2:2024 ISO/IEC FDIS-Data quality me..., 25012:2008 ISO/IEC-Data quality mo..., 29119-11:2020 ISO/IEC TR-Guidelines on ... (Accuracy); 5259-2:2024 ISO/IEC FDIS-Data quality me... (Bias detection and correction); 25059:2023 ISO/IEC-Quality model f..., 24029-1:2021 ISO/IEC TR-Assessment of l..., 24029-2:2023 ISO/IEC FDIS-Assessment of l... (Robustness); 5259-2:2024 ISO/IEC FDIS-Data quality me... 22989:2022 ISO/IEC-Artificial int... (Data quality reporting); 5259-1:2024 ISO/IEC-Overview, termi..., 31010:2019 IEC-Risk assessment, (Data collection processes); 24027:2021 ISO/IEC TR-Bias in Al syst..., 5338:2023 ISO/IEC-Al System life ..., 17847 ISO/IEC TS-Verification an..., 22443 ISO/IEC AWI TS-Guidance on add..., 5339:2024 ISO/IEC Guidance for Al..., 62304:2006 IEC-Medical device ... (Lifecycle); 25024:2015 ISO/IEC-Measurement of ..., 42001:2023 ISO/IEC-Management system..., 27000:2018 ISO/IEC-Information sec..., (Measurement and method); 5259-2:2024 ISO/IEC FDIS-Data quality me... (Origin of data); 25059:2023 ISO/IEC-Quality model f..., 25010-2023 ISO/IEC-Quality model f..., 24028:2020 ISO/IEC TR-Overview of tru..., 9868 ISO/IEC DIS-Biometric ident..., 42006:2024 ISO/IEC DIS-Requirements fo..., (Security); 22989:2022 ISO/IEC-Artificial int... (Cybersecurity)	( 1 ) The purpose of this Regulation is to improve the functioning of the	
		65   Robustness achieved with redundancy, backup of fail-safe plan				( )
		29   Data collection processes		5259-1:2024 ISO/IEC, 31010:2019 IEC		
		50   Measurement and method		25024:2015 ISO/IEC, 42001:2023 ISO/IEC, 27000:2018 ISO/IEC		
		46   HR AI Systems				
		13   Bias detection and correction		5259-2:2024 ISO/IEC FDIS		
		49   Lifecycle		24027:2021 ISO/IEC TR, 5338:2023 ISO/IEC, 17847 ISO/IEC TS, 22443 ISO/IEC AWI TS, 5339:2024 ISO/IEC, 62304:2006 IEC		
		48   Level declaration & instruction of use				
		66   Security		25059:2023 ISO/IEC, 25010:2023 ISO/IEC, 24028:2020 ISO/IEC TR, 9868 ISO/IEC DIS, 42006:2024 ISO/IEC DIS		
		41   Examination of biases, health and safety of persons				
		52   Origin of data		5259-2:2024 ISO/IEC FDIS		
		Link <a href="https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689">https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689</a>	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. 2. To address the technical aspects of how to measure the appropriate levels of accuracy and robustness set out in		
OPTIONAL INFORMATION						
		Name and Surname	Affiliation and UNI CT 533 (member) Qualification UNI CT 504 (president)		LinkedIn <a href="https://www.linkedin.com/in/domenico-natale-a9b99812/">https://www.linkedin.com/in/domenico-natale-a9b99812/</a> ... other originalSubdomain=it	
		Observations				

  

Specification	Relationship with Standard	Article 016				Whereas
		Terms	% Variant	Text	Standard	
		222   Providers				2   ( )
		4   AI systems		25098:2023 ISO/IEC, 5338:2023 ISO/IEC, 24008:2024 ISO/IEC TR, 24028:2020 ISO/IEC TR-Overview of tru..., 6254 ISO/IEC CD-TS-Objective and a..., 17847 ISO/IEC TS-Verification an..., 22443 ISO/IEC AWI TS-Guidance on add..., 21221 ISO/IEC WD-Beneficial AI s..., 25059-1 ISO/IEC AWI-Quality model f..., 25223:2024 ISO/IEC AWI TS-Guidance and re..., 42006:2024 ISO/IEC DIS-Requirements fo..., 42005:2024 ISO/IEC DIS-AI system impac..., (AI systems); 42001:2023 ISO/IEC-Management syst..., 27000:2018 ISO/IEC-Information sec..., 42006:2024 ISO/IEC DIS-Requirements fo..., (Conformity); 82079-1:2019 IEC/IEEE-IEC Part 1: pri... (Documentation)	38	
		247   Documentation		82079-1:2019 IEC/IEEE		
		289   Quality management				
		305   Contact				
		144   Conformity		42001:2023 ISO/IEC, 27000:2018 ISO/IEC, 42006:2024 ISO/IEC DIS		
		Link <a href="#">Link</a>	Full text	Obligations of providers of high-risk AI systems Providers of high-risk AI systems shall: (a) ensure that their high-risk AI systems are compliant with the requirements set out in Section 2; (b) indicate on the high-risk AI system or, where that is not possible, on its packaging or its accompanying documentation, as applicable, their name, registered trade name or registered trade mark, the address at which they		
OPTIONAL INFORMATION						
		Name and Surname	Affiliation and Qualification		LinkedIn ... other	
		Observations				

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Specification	Relationship with Standard	Article 017				Whereas
		Terms	% Variant	Text	Standard	
		22   Data holder		5259-2-2024 ISO/IEC FDIS		( )
		86   Leadership		42001:2023 ISO/IEC, 23894:2023 ISO/IEC		
		49   Lifecycle		24027:2021 ISO/IEC TR, 5338:2023 ISO/IEC, 17847 ISO/IEC TS, 22443 ISO/IEC AWI TS, 5339:2024 ISO/IEC, 62304:2006 IEC		
		58   Re-use of the personal data	Quality control			
		71   The personal data in the special categories of personal data are deleted				
		84   Assessment datasets				
		30   Data life cycle		8183:2023 ISO/IEC, 5259-1:2024 ISO/IEC, 5259-4:2024 ISO/IEC		
		3   AI models		25059:2023 ISO/IEC, 25059-1 ISO/IEC AWI		
		80   Cleaning		42001:2023 ISO/IEC		
		87   Planning		42001:2023 ISO/IEC		
		21   Compliance		25058:2015 ISO/IEC, 5259-2:2024 ISO/IEC FDIS, 25019:2023 ISO/IEC, 25012:2020 ISO/IEC		
		24   Identifiability		5259-4:2024 ISO/IEC FDIS		
		Link <a href="https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689">https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689</a>	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 include at least the following aspects: (a) a strategy for regulatory compliance, including compliance with conformity assessment procedures and		
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		Observations				
Specification	Relationship with Standard	Article 018				Whereas
		Terms	% Variant	Text	Standard	
		222   Providers			39	( )
		246   Technical documentation		82079-1:2019 ISO/IEC		
		289   Quality management			39	
		144   Conformity		42001:2023 ISO/IEC, 27000:2018 ISO/IEC, 42006:2024 ISO/IEC DIS	39	
		Link	Full text	Documentation keeping 1. The provider shall, for a period ending 10 years after the high-risk AI system has been placed on the market or put into service, keep at the disposal of the national competent authorities: (a)the technical documentation referred to in Article 11; (b)the documentation concerning the quality management system referred to in Article 17;		
		OPTIONAL INFORMATION				
		Name and Surname		Affiliation and Qualification	LinkedIn	
		Observations				

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Article 071

## *Specification*

- EU database for high-risk AI systems listed in Annex III

## *Relationship with Standard*

25024/2015 ISO/IEC-Measurement of ... 5529-2:2024 ISOIEC  
FDI-Fatigue quality me., 25059-2023 ISO/IEC-Quality model f...,  
25019/2023 ISO/IEC-Quality-in-use, 25018/2008 ISO/IEC-Quality  
Data quality mo., (Accessibility) 25059-2023 ISO/IEC-Quality  
model f..., 5338/2023 ISOIEC-AL System life ..., 24030/2024  
ISOIEC TR\_Use-cases ..., 24028/2020 ISO/IEC TR-Overview of  
tru ..., 6254 ISOIEC CD TS-Objectives and ..., 17847 ISO/IEC  
TS-Verification an ..., 22443 ISO/IEC AWI TS-Guidance on add ...,  
21221 ISO/IEC WD-Beneficial Al s ..., 25059-1 ISOIEC AWI-  
Quality model f..., 25223/2024 ISO/IEC AWI TS-Guidance and  
re ..., 42006-2024 ISO/IEC DIS-Requirements fo ..., 42005/2024  
ISO/IEC DIS-Al system impac ..., [Al systems], 25019/2023  
ISO/IEC-Quality-in-use ..., 26514/2022 ISO/IEC/IEEE-Design and  
dev ..., 21221 ISO/IEC WD-Beneficial Al s ..., [User] 25024/2015  
ISO/IEC-Measurement of ... 5529-2:2024 ISOIEC-FDI-Quality  
Data-quality me ..., 42001/2023 ISO/IEC-Management-system...,  
24028/2020 ISO/IEC TR-Overview of tru ..., 25223/2024 ISO/IEC  
AWI TS-Guidance and re ..., 5299-6/2024 CD TR-Visualization ...  
(Data)

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

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EU database for high-risk AI systems listed in Annex III  
1. The Commission shall, in collaboration with the Member States, set up and maintain an EU database containing information referred to in paragraphs 2 and 3 of this Article concerning high-risk AI systems referred to in Article 6(2) which are registered in accordance with Articles 49 and 60 and AI systems that are not considered as high-risk pursuant to Article 6(3) and which are registered in accordance with Article 6(4) and Article 49. When setting the

**Article 072**

## *Specification*

Post-market monitoring by providers and post-market monitoring plan for high-risk AI systems	
25059-2023 ISO/IEC-Quality model f...	5333-2023 ISO/IEC-Quality model f...
System life ...	24030-2024 ISO/IEC TR-Use cases.
24028-2020 ISO/IEC TR-Overview of tru...	6254 ISO/IEC COBIT 5.1
Objective and a ...	17847 ISO/IEC TS-Verification art...
ISO/IEC AWI TS-Guidance on add ...	22121 ISO/IEC TS-Guidance on add ...
Beneficial AI ...	25059-1 ISO/IEC AWI-Quality model ...
25223-2024 ISO/IEC AWI TS-Guidance and re...	42066:2024 ISO/IEC TS-Guidance and re...
ISO/IEC DIS-Requirements for ...	42005:2024 ISO/IEC DIS-Requirements for ...
system impact ...	[All systems]; 25019:2023 ISO/IEC-Quality-in-
[Post-market];	use ...
27000:2018 ISO/IEC-Information sec...	[Documented information]; 82079-1:2019 IEC/IEEE-IEC Part 1: pri...
7000:2018 ISO/IEC-Management sys...	[Documentation]

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

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| Post-market monitoring by providers and post-market monitoring plan for high-risk AI systems

1. Providers shall establish and document a post-market monitoring system in a manner that is proportionate to the nature of the AI technologies and the risks of the high-risk AI system.
2. The post-market monitoring system shall actively and systematically collect, document and analyse relevant data which may be provided by deployers or which may be collected through other sources on the performance of high-risk AI systems.

**OPTIONAL INFORMATION**

Name and  
Surname

