

Zoznam požadovaných technických noriem Úradom pre normalizáciu, metrológiu a skúšobníctvo Slovenskej republiky používaných na akreditáciu na účely notifikácie podľa jednotlivých technických predpisov z oblasti posudzovania zhody

List of Required standards by notifying authority ÚNMS SR for accreditation for authorization and notification purpose per legislation

P. č.	Oblasť posudzovania zhody/ Conformity assessment area	Právny predpis SR/ Slovak legislation	Postupy posudzovania zhody (moduly)/ Conformity assessment procedures	Príloha č./ ANNEX	Akreditácia/ Accreditation – preferované technické normy podľa EA-2/17 M:2020 (MSA-N/01)/ PREFERRED STANDARDS according to EA-2/17 M:2020 (MSA-N/01)/	Požadovaná technická norma ÚNMS SR, ktorý je notifikujúcim orgánom, používaná pri akreditácii na účely notifikácie/ Required standards by notifying authority ÚNMS SR for accreditation for authorization and notification purpose	Odporúčaná technická norma ÚNMS SR, ktorou sa zabezpečuje podpora činností podľa požadovanej technickej normy/ Reccomended standard by UNMS SR, which ensures the support of activities according to the required standard
1.	90/385/EEC Active implantable medical devices	NV SR 167/2020 Z. z.	EC DECLARATION OF CONFORMITY (Complete quality assurance system)	ANNEX 2	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
			EC TYPE-EXAMINATION	ANNEX 3	17065	17065	17025
			EC VERIFICATION	ANNEX 4	17065	17065	17025
			EC DECLARATION OF CONFORMITY TO TYPE (Assurance of production quality)	ANNEX 5	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
2.	92/42/EEC Hot-water boilers	Zákon 529/2010 Z. z. NV SR 236/2015 Z. z.	Module B: EC type-examination	ANNEX III	17065	17065	17025
			Module C: Conformity to type	ANNEX IV	17065	17065	
			Module D: Production quality assurance	ANNEX IV	17065	17065 System Access (1*+ qa)	

						17065 + 17021-1	
			Module E: Product quality assurance	ANNEX IV	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
3.	93/42/EEC Medical devices		EC DECLARATION OF CONFORMITY (Full quality assurance system)	ANNEX II	17021-1	17065 System Access (1*+ qa) 17065 + 17021-1	
			EC TYPE-EXAMINATION	ANNEX III	17065	17065	17025
			EC VERIFICATION	ANNEX IV	17065	17065	17025
			EC DECLARATION OF CONFORMITY (Production quality assurance)	ANNEX V	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
			EC DECLARATION OF CONFORMITY (Product quality assurance)	ANNEX VI	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
4.	98/79/EC In vitro diagnostic medical devices	NV SR 569/2001 Z. z.	EC DECLARATION OF CONFORMITY	ANNEX III	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
			EC DECLARATION OF CONFORMITY (FULL QUALITY ASSURANCE SYSTEM)	ANNEX IV	17021-1	17065 System Access (1*+ qa) 17065 + 17021-1	
			EC TYPE-EXAMINATION	ANNEX V	17065	17065	17025
			EC VERIFICATION	ANNEX VI	17065	17065	17025
			EC DECLARATION OF CONFORMITY (PRODUCTION QUALITY ASSURANCE)	ANNEX VII	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
5.	2000/14/EC Noise emission in the environment by equipment for use outdoors	NV SR 78/2019 Z. z.	EC DECLARATION OF CONFORMITY	ANNEX II			
			METHOD OF MEASUREMENT OF	ANNEX III			

			AIRBORNE NOISE EMITTED BY EQUIPMENT FOR USE OUTDOORS				
			Internal control of production	Annex V			
			Internal control of production with assessment of technical documentation and periodical checking	Annex VI	17065	17065	17025
			Unit verification	Annex VII	17065	17065	17025
			Full quality assurance	Annex VIII	17021-1	17065 System Access (1*+ qa) 17065 + 17021-1	
6.	2006/42/EC Machinery	NV SR 436/2008 Z. z.	EC type-examination Modul B	Annex IX - Art. 12 (3) (b) and (4) (a)	17065	17065	17025
			Full quality assurance Modul H	Annex X - Art. 12 (3) (c) and (4) (b)	17021-1	17065 System Access (1*+ qa) 17065 + 17021-1	
7.	2009/48/EC Safety of toys	Zákon 78/2012 Z. z.	EC type-examination	Article 20	17065	17065	17025
8.	2010/35/EU Transportable pressure equipment	Zákon 254/2011 Z. z.	Conformity assessment activities	Section I.1 of Annex I, Section II.1 of Annex II, and Section III.1 of Annex III to Directive 2008/68/EC	17020	17020 System Access (1*+ t + cd) 17020 + 17065	
			Exceptional checks	Section I.1 of Annex I, Section II.1 of Annex II, and Section III.1 of Annex III to Directive 2008/68/EC	17020	17020	

			Intermediate inspections	Section I.1 of Annex I, Section II.1 of Annex II, and Section III.1 of Annex III to Directive 2008/68/EC	17020	17020	
			Periodic inspections	Section I.1 of Annex I, Section II.1 of Annex II, and Section III.1 of Annex III to Directive 2008/68/EC	17020	17020	
			Reassessment of conformity	Annex III to Directive 2010/35/EU	17020	17020	
9.	2013/29/EU Pyrotechnic articles	NV SR 70/2015 Z. z	EU type-examination	Annex II - Module B	17065	17065	17025
			Conformity to type based on internal production control plus supervised product random checks	Annex II - Module C2	17065	17065	17025
			Production quality assurance	Annex II - Module D	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
			Product quality assurance	Annex II - Module E	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
			Unit verification	Annex II - Module G	17065	17065	17025
			Full quality assurance (only for category 4 fireworks)	Annex II - Module H	17021-1	17065 System Access (1*+ qa) 17065 + 17021-1	

10.	2013/53/EU Recreational craft and personal watercraft	NV SR 77/2016 Z. z	Internal production control plus supervised product testing (module A1)	Annex II of Decision 768/2008/EC	17020	17020	
			EU-type examination (Module B)	Annex II of Decision 768/2008/EC	17065	17065	17020 or 17025
			Conformity to type based on internal production control (Module C)	Annex II of Decision 768/2008/EC	17065	17065	17020 or 17025
			Conformity to type based on internal production control plus supervised product testing (Module C1)	Annex II of Decision 768/2008/EC	17020	17020	
			Conformity to type based on quality assurance of the production process (Module D)	Annex II of Decision 768/2008/EC	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
			Conformity to type based on product quality assurance (Module E)	Annex II of Decision 768/2008/EC	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
			Conformity to type based on product verification (Module F)	Annex II of Decision 768/2008/EC	17065	17065	17020 or 17025
			Conformity based on unit verification (Module G)	Annex II of Decision 768/2008/EC	17065	17065	17020 or 17025
			Conformity based on full quality assurance (module H)	Annex II of Decision 768/2008/EC	17021-1	17065 System Access (1*+ qa) 17065 + 17021-1	
			Equivalent conformity based on post-construction assessment	Annex V of Directive 2013/53/EU	17065	17065	17020 or 17025
11.	2014/28/EU Explosives for civil uses	NV SR 131/2016 Z. z.	EU-type examination (Module B)	Annex III	17065	17065	17025
			Internal production control plus supervised product checks at random intervals (Module C2)	Annex III	17065	17065	17025

			Production process quality assurance (Module D)	Annex III	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
			Product quality assurance (Module E)	Annex III	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
			Product verification (Module F)	Annex III	17065	17065	17025
			Unit verification (Module G)	Annex III	17065	17065	17025
12.	2014/29/EU Simple pressure vessels	NV SR 234/2015 Z. z.	EU-type examination (Module B)	Annex II	17065	17065	17025 or 17020
			Conformity to type based on internal production control plus supervised product testing (Module C1)	Annex II	17065	17065	17020 or 17025
			Conformity to type based on internal production control (Module C)	Annex II	17020	17065	17020 or 17025
			Conformity to type based on internal production control plus supervised product checks at random intervals (Module C2)	Annex II	17065 (17020)	17065 (17065 + 17020)	17020 or 17025
13.	2014/30/EU Electromagnetic compatibility	NV SR 127/2016 Z. z.	EU type examination procedure (Module B)	Annex III [EU type examination procedure (Module B) followed by Conformity to type based on internal production control (Module C)]	17065	17065	17025
14.	2014/31/EU Non-automatic weighing instruments	NV SR 126/2016 Z. z.	EU type-examination	Annex II - Module B	17065	17065	

			Conformity to type based on quality assurance of the production process	Annex II - Module D	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
			Quality assurance of the production process	Annex II - Module D1	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
			Conformity to type based on product verification	Annex II - Module F	17065	17065	17025
			Conformity based on product verification	Annex II - Module F1	17065	17065	17025
			Conformity based on unit verification	Annex II - Module G	17065	17065	17025
15.	2014/32/EU Measuring Instruments Directive	NV SR 145/2016 Z. z	Internal production control plus supervised instrument checks at random intervals	Annex II - Module A2	17065	17065	17025
			EU type-examination	Annex II - Module B	17065	17065	17025
			Conformity to type based on internal production control plus supervised pressure equipment checks at random intervals	Annex II - Module C2	17065	17065	17025
			Conformity to type based on quality assurance of the production	Annex II - Module D	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
			Quality assurance of the production process	Annex II - Module D1	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
			Conformity to type based on instrument quality assurance	Annex II - Module E	17065	17065 System Access (1*+ qa) 17065 + 17021-1	

			Quality assurance of final instrument inspection and testing	Annex II - Module E1	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
			Conformity to type based on instrument verification	Annex II - Module F	17065	17065	17025
			Conformity based on instrument verification	Annex II - Module F1	17065	17065	17025
			Conformity based on unit verification	Annex II - Module G	17065	17065	17025
			Conformity based on full quality assurance	Annex II - Module H	17021-1	17065 System Access (1*+ qa) 17065 + 17021-1	
			Conformity based on full quality assurance plus design examination	Annex II - Module H1	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
16.	2014/33/EU Lifts and safety components for lifts	NV SR 235/2015 Z. z.	EU-type examination of safety components for lifts	Annex IVA	17065	17065	17020
			EU-type examination of lifts	Annex IVB	17065	17065	17020
			Final inspection for lifts	Annex V	17020	17020	
			Conformity to type based on product quality assurance for safety components for lifts	Annex VI	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
			Conformity based on full quality assurance for safety components for lifts	Annex VII	17021-1	17065 System Access (1*+ qa) 17065 + 17021-1	
			Conformity based on unit verification for lifts	Annex VIII	17020	17020	

			Conformity to type with random checking for safety components for lifts	Annex IX		17020	
			Conformity to type based on product quality assurance for lifts	Annex X	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
			Conformity based on full quality assurance plus design examination for lifts	Annex XI	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
			Conformity to type based on production quality assurance for lifts	Annex XII	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
17.	2014/34/EU Equipment and protective systems intended for use in potentially explosive atmospheres (recast)	NV SR 149/2016 Z. z	EU-type examination (Module B)	Annex III	17065	17065	17025 or 17020
			Conformity to type based on quality assurance of the production process (Module D)	Annex IV	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
			Conformity to type based on product verification (Module F)	Annex V	17065	17020	
			Conformity to type based on internal production control plus supervised product testing (Module C1)	Annex VI	17065	17065	17020
			Conformity to type based on product quality assurance (Module E)	Annex VII	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
			Internal Production Control (Module A) and the communication of the technical documentation as Art. 13.1(b)(ii)	Annex VIII		17020	
			Conformity based on unit verification (Module G)	Annex IX	17065	17020	

18.	2014/53/EU Radio equipment	NV SR 193/2016 Z. z.	Conformity assessment modules B (EU-type examination)	Article 17 and Annex III	17065	17065	17025
			Conformity assessment module H (conformity assessment based on full quality assurance)	Article 17 and Annex IV	17021-1	17065 System Access (1*+ qa) 17065 + 17021-1	
19.	2014/68/EU Pressure equipment	NV SR 1/2016 Z. z	Internal production control plus supervised pressure equipment checks at random intervals	Annex III - Module A2	17020	17020	
			EU-Type examination – production type	Annex III - Module B	17065	17065	17020
			EU-Type examination – design type	Annex III - Module B	17065	17065	
			Conformity to type based on internal production control plus supervised pressure equipment checks at random intervals	Annex III - Module C2	17065	17020	
			Conformity to type based on quality assurance of the production process	Annex III - Module D	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
			Quality assurance of the production process	Annex III - Module D1	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
			Conformity to type based on pressure equipment quality assurance	Annex III - Module E	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
			Quality assurance of final pressure equipment inspection and testing	Annex III - Module E1	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
			Conformity to type based on pressure equipment verification	Annex III - Module F	17065	17020	

			Conformity based on unit verification	Annex III – Modul G	17065	17020	
			Conformity based on full quality assurance	Annex III - Module H	17021-1	17065 System Access (1*+ qa) 17065 + 17021-1	
			Conformity based on full quality assurance plus design examination	Annex III - Module H1	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
			European approval for materials	Article 15	17065	17020	
			Approval of permanent joining personnel	Annex I, 3.1.2	17024	17024	
			Approval of permanent joining procedures	Annex I, 3.1.2	17020	17020	
			Approval of non-destructive testing personnel (RTPO)	Annex I, 3.1.3	17024	17024	
20.	2014/90/EU Marine equipment	NV SR 262/2016 Z. z	EC type-examination	Art. 15.2 (a), Annex II - Module B	17065	17065	17020 or 17025
			Production quality assurance	Art. 15.2 (a), Annex II - Module D	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
			Product quality assurance	Art. 15.2 (a), Annex II - Module E	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
			Product verification	Art. 15.2 (a), Annex II - Module F	17065	17065	17020 or 17025
			Unit verification	Art. 15.2 (b), Annex II - Module G	17065	17065	17020 or 17025

21.	2016/797 on the interoperability of the rail system	Zákon 513/2009 Z. z.	EC declaration of conformity or suitability for use of interoperability constituents	Article 9 (2) Modul CA1, CA2, CB, CD, CF, CH, SG, SH1	17065	17065 ERA 000MRA1044	
			EC verification procedure for subsystems	Annex IV	17065	17065 ERA 000MRA1044	
22.	Regulation (EU) 2016/425 Personal protective equipment		EU type-examination	Annex V (Modul B)	17065	17065	17025
			Supervised product checks at random intervals	Annex VII (Modul C2)	17065	17065	17025
			Quality assurance of the production process	Annex VIII	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
23.	Regulation (EU) 2017/746 on in vitro diagnostic medical devices		Conformity assessment based on a quality management system	Annex IX(I)		Regulation (EU) 2017/746	
			Conformity assessment based on assessment of technical documentation	Annex IX(II)		Regulation (EU) 2017/746	
			Conformity assessment based on type-examination	Annex X		Regulation (EU) 2017/746	17025
			Conformity assessment based on product quality assurance	Annex XI		Regulation (EU) 2017/746	
24.	Regulation (EU) 2017/745 on medical devices		Conformity assessment based on a quality management system	Annex IX(I)		Regulation (EU) 2017/745 on medical devices	
			Conformity assessment based on assessment of technical documentation	Annex IX(II)		Regulation (EU) 2017/745 on medical devices	
			Conformity assessment based on type-examination	Annex X		Regulation (EU) 2017/745 on medical devices	

			Conformity assessment based on product quality assurance	Annex XI(A)		Regulation (EU) 2017/745 on medical devices	
			Conformity assessment based on product conformity verification	Annex XI(B)		Regulation (EU) 2017/745 on medical devices	
25.	Regulation (EU) 2016/426 Appliances burning gaseous fuels		EU-Type Examination - Production type	Annex III - Module B	17065	17065	17025
			Conformity to type based on internal production control plus supervised product checks at random intervals	Annex III - Module C2	17065	17065	17025
			Conformity to type based on quality assurance of the production process	Annex III - Module D	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
			Conformity to type based on product quality assurance	Annex III - Module E	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
			Conformity to type based on product verification	Annex III - Module F	17065	17065	17025
			Conformity based on unit verification	Annex III - Module G	17065	17065	17025
26.	Regulation (EU) 2019/945 on unmanned aircraft systems and on third-country operators of unmanned aircraft systems		Conformity based on full quality assurance as per Annex II to Decision No 768/2008/EC (Modul H)	Annex Part 9	17021-1	17065 System Access (1*+ qa) 17065 + 17021-1	
			EU-type examination (Modul B)	Annex Part 8	17065	17065	17025 or 17020
			Conformity to type based on internal production control (Module C)	Annex Part 8	17065	17065	17025 or 17020

27.	Regulation (EU) 2016/424 Cableway installations		EU-type examination - production type (Module B)	Annex III	17065	17065	17020
			Conformity to type based on quality assurance of the production process (Module D)	Annex IV	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
			Conformity to type based on subsystem or safety component verification (Module F)	Annex V	17065	17065	17020
			Conformity based on unit verification (Module G)	Annex VI	17065	17065	17020
			Conformity based on full quality assurance plus design examination (Module H 1)	Annex VII	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
28.	Regulation (EC) No 552/2004 - Interoperability of the European Air Traffic Management network		EC declaration of conformity and suitability for use of interoperability constituents	Annex III			
			EC declaration of verification of systems	Annex IV			
29.	Decision 2009/750/EC (implementing Directive 2004/52/EC) - Interoperability of Electronic Road Toll Systems		Assessment of Suitability for Use	Article 2(f)			
			Assessment of Conformity to Specifications	Annexes II, III & IV			
			Assessment of Conformity to Specifications	Articles 12, 13 & 14			
30.	Regulation (EU) 2019/1009 on EU fertilising products		EU-TYPE EXAMINATION (MODULE B) FOLLOWED BY CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL (MODULE C)	Annex IV Article ...	17065	17065	17025
			INTERNAL PRODUCTION CONTROL plus supervised product testing (modul A1)	Articles 13, 14(2)-(3), 15, 16, 20-36, Annex	17020	17065	17025

			QUALITY ASSURANCE OF THE PRODUCTION PROCESS (Modul D1)	Articles 13, 14(2)-(3), 15, 16, 20-36, Annex IV, Part I, Point	17065	17065 System Access (1*+ qa) 17065 + 17021-1	
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