

**Notification of a Body in the framework of technical harmonization directive**

<b>Reference</b>	Directive: 93/42/EEC Medical devices
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From	To
Czech Office for Standards, Metrology and Testing Biskupský dvůr 1148/5 110 00 Praha 1 Czech Republic	<b>European Commission</b> Enterprise Directorate-General - B 1049 Brussels  and to other Member States

Name of the Designating Authority	Competence assessment performed by
Czech Office for Standards, Metrology and Testing	Czech Office for Standards, Metrology and Testing

<b>Body name, address, telephone, fax, email, website</b> ELEKTROTECHNICKY ZKUŠEBNÍ ÚSTAV, s.p. Pod lísem 129/2, Troja, 182 00 Praha 8
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<b>Identification number of the body</b>	NB 1014
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<b>Basis of competence assessment</b>
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COMMISSION IMPLEMENTING REGULATION (EU) No 920/2013

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**1. Medical devices, non-active, 93/42/EEC, competence for the selected product(s) and procedure(s)**

<sup>1</sup>Mark selected products and procedures with a cross (x) in the gray boxes.  
 Annex II: Full quality assurance system; Annex III: EC type-examination; Annex IV: EC verification;  
 Annex V: Production quality assurance; Annex VI: Product quality assurance

<sup>2</sup>Specify limitations (Annexes and/or products) where applicable

MD 0000 MD 0100	Medical Devices, Non-Active General non-active, non-implantable medical devices	<sup>1</sup> Annexes			<sup>2</sup> Limitations		
		II	III	IV	V	VI	
MD 0101	Non-active devices for anaesthesia, emergency and intensive care	x			x		
MD 0102	Non-active devices for injection, infusion, transfusion and dialysis	x			x		
MD 0103	Non-active orthopaedic and rehabilitation devices						
MD 0104	Non-active medical devices with measuring function	x			x		
MD 0105	Non-active ophthalmologic devices						
MD 0106	Non-active instruments	x			x		
MD 0107	Contraceptive medical devices						

MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing	X				X			excluding devices for disinfecting
MD 0109	Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)								
MD 0110	Non-active medical devices for ingestion								
MD 0200	<b>Non-active implants</b>	II	III	IV	V	VI			
MD 0201	Non-active cardiovascular implants								
MD 0202	Non-active orthopaedic implants	X			X				
MD 0203	Non-active functional implants	X			X				
MD 0204	Non-active soft tissue implants	X			X				excluding non-absorbable soft tissue implants (e.g. breast implants, non-absorbable derma fillers)
MD 0300	<b>Devices for wound care</b>	II	III	IV	V	VI			
MD 0301	Bandages and wound dressings	X			X				
MD 0302	Suture material and clamps	X			X				
MD 0303	Other medical devices for wound care	X			X				

	Medical Devices, Non-Active	<sup>1</sup> Annexes						<sup>2</sup> Limitations						
		II	III	IV	V	VI	II	III	IV	V	VI			
MD 0400	<b>Non-active dental devices and accessories</b>													
MD 0401	Non-active dental equipment and instruments	X			X									
MD 0402	Dental materials	X			X									
MD 0403	Dental implants	X			X									

**2. Medical devices, active, 93/42/EEC, competence for the selected product(s) and procedure(s)**

<sup>1</sup>Mark selected products and procedures with a cross (X) in the gray boxes.  
Annex II: Full quality assurance system; Annex III: EC type-examination; Annex IV: EC verification;  
Annex V: Production quality assurance; Annex VI: Product quality assurance

<sup>2</sup>Specify limitations (Annexes and/or products) where applicable

	Medical Devices, Active	<sup>1</sup> Annexes						<sup>2</sup> Limitations						
		II	III	IV	V	VI	II	III	IV	V	VI			
MD 1000	<b>Medical Devices, Active</b>													
MD 1100	<b>General active medical devices</b>													
MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis	X			X									excluding devices for extra corporeal circulation

MD 1000	Medical Devices, Active	<sup>1</sup> Annexes				<sup>2</sup> Limitations
		X			X	
MD 1102	Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	X			X	excluding hyperbaric chambers for oxygen therapy
MD 1103	Devices for stimulation or inhibition	X			X	
MD 1104	Active surgical devices	X			X	
MD 1105	Active ophthalmologic devices					
MD 1106	Active dental devices					
MD 1107	Active devices for disinfection and sterilisation					
MD 1108	Active rehabilitation devices and active prostheses	X			X	excluding active prostheses
MD 1109	Active devices for patient positioning and transport	X			X	
MD 1110	Active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)					
MD 1111	Software					
MD 1112	Medical gas supply systems and parts thereof	X			X	

MD 1000	Medical Devices, Active	<sup>1</sup> Annexes						<sup>2</sup> Limitations
		II	III	IV	V	VI		
MD 1200	Devices for imaging						VI	
MD 1201	Imaging devices utilising ionizing radiation							
MD 1202	Imaging devices utilising non-ionizing radiation							
MD 1300	Monitoring devices	II	III	IV	V	VI		
MD 1301	Monitoring devices of non-vital physiological parameters	X			X			
MD 1302	Monitoring devices of vital physiological parameters	X			X			
MD 1400	Devices for radiation therapy and thermo therapy	II	III	IV	V	VI		
MD 1401	Devices utilising ionizing radiation							
MD 1402	Devices utilising non-ionizing radiation	X			X			
MD 1403	Devices for hyperthermia / hypothermia	X			X			
MD 1404	Devices for (extracorporeal) shock-wave therapy (lithotripsy)							

3. Medical devices, 93/42/EEC, competence for the selected specifics

<sup>1</sup>Mark selected specifics with a cross (x) in the gray boxes.

<sup>2</sup>Specify limitations, when they are applicable. Without any limitation, each specific item is applicable to the chosen scopes under MD 0000 and MD 1000.

MDS 7000	Specifics of Medical Devices	<sup>1</sup> Select	<sup>2</sup> Limitations
MDS 7001	Medical devices incorporating medicinal substances, according to Directive 2001/83/EC	x	
MDS 7002	Medical devices utilising tissues of animal origin, including Commission Regulation (EU) No 722/2012 <sup>1</sup>		
MDS 7003	Medical devices incorporating derivatives of human blood, according to Directive 2000/70/EC, amended by Directive 2001/104/EC		
MDS 7004	Medical devices referencing the Directive 2006/42/EC on machinery	x	
MDS 7005	(currently not used)		
MDS 7006	Medical devices in sterile condition	x	Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam)
MDS 7007	Medical devices utilising micromechanics		
MDS 7008	Medical devices utilising nanomaterials		
MDS 7009	Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed	x	
MDS 7010	Medical devices incorporating software / utilising software / controlled by software	x	

<sup>1</sup> Until 28 August 2013 Directive 2003/32/EC



