Notification of a Body in the framework of technical harmonization directive

Reference	Directive: 93/42/EEC Medical devices

From	To
Czech Office for Standards, Metrology and Testing Biskupský dvůr 1148/5 110 00 Praha 1 Czech Republic	**European Commission** 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

Body name, address, telephone, fax, email, website
ELEKTROTECHNICKY ZKUŠEBNÍ USTAV, s.p. Pod lisem 129/2, Trója, 182 00 Praha 8

Identification number of the body	NB 1014

Basis of competence assessment

Doručovací číslo: PSČ 171 02 Czech Republic Phone: +420 266 104 111 Fax: +420 284 680 037	COMMISSION IMPLEMENTING REGULATION (EU) No 920/2013

Notification date	06/05/2004
Created or last update	18/09/2019
Period of validity of the notification	25/05/2020

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

[1]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

[2]Specify limitations (Annexes and/or products) where applicable

MD 0000	**Medical Devices, Non-Active**	**[1]Annexes**					**[2]Limitations**
MD 0100	**General non-active, non-implantable medical devices**	**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	**Non-active implants**	**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	**Devices for wound care**	**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		

MD 0000	**Medical Devices, Non-Active**	**[1]Annexes**					**[2]Limitations**
MD 0400	**Non-active dental devices and accessories**	**II**	**III**	**IV**	**V**	**VI**	
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)

[1]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

[2]Specify limitations (Annexes and/or products) where applicable

MD 1000	**Medical Devices, Active**	**[1]Annexes**					**[2]Limitations**
MD 1100	**General active medical devices**	**II**	**III**	**IV**	**V**	**VI**	
MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis	x			x		excluding devices for extra corporeal circulation

MD 1000	Medical Devices, Active	[1]Annexes					[2]Limitations
MD 1102	Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	x			x		excluding hyperbaric chambres 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	[1]Annexes					[2]Limitations
MD 1200	**Devices for imaging**	**II**	**III**	**IV**	**V**	**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 (extracorporal) shock-wave therapy (lithotripsy)						

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

[1]Mark selected specifics with a cross (x) in the gray boxes.

[2]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	[1]Select	[2]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[1]		
MDS 7003	Medical devices incorporating derivates 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	

[1] Until 28 August 2013 Directive 2003/32/EC