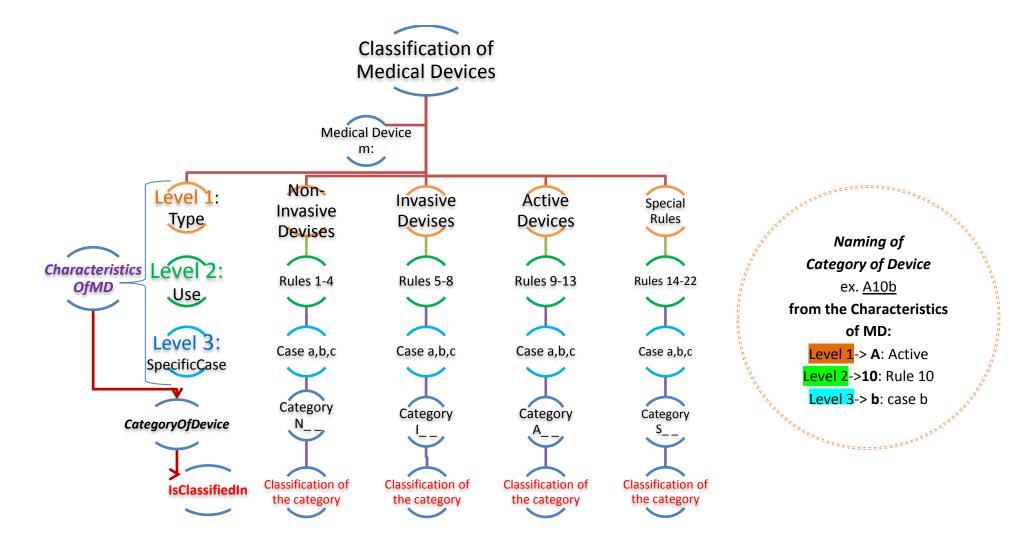
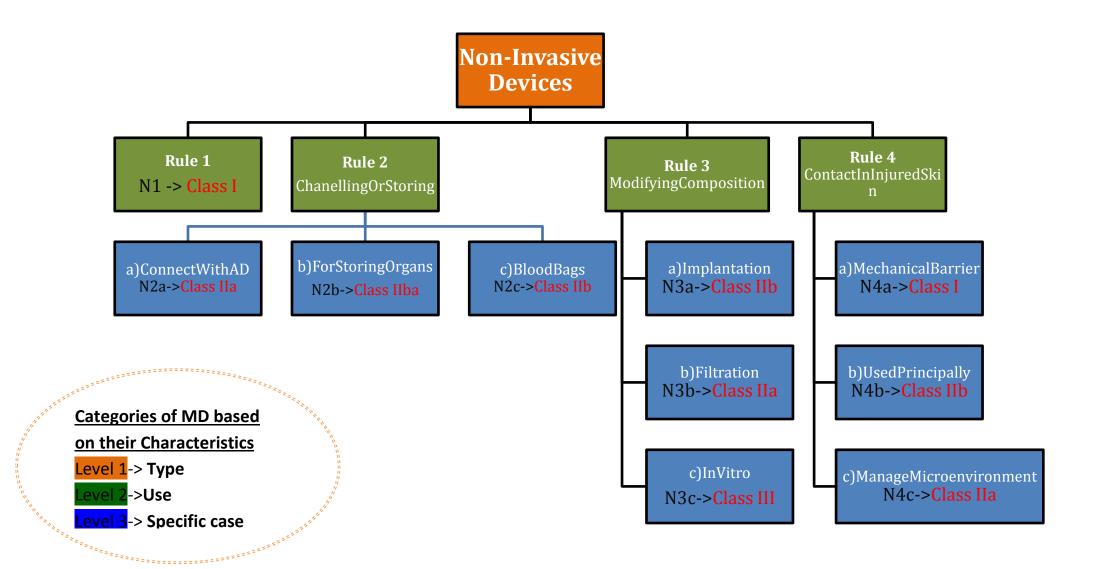
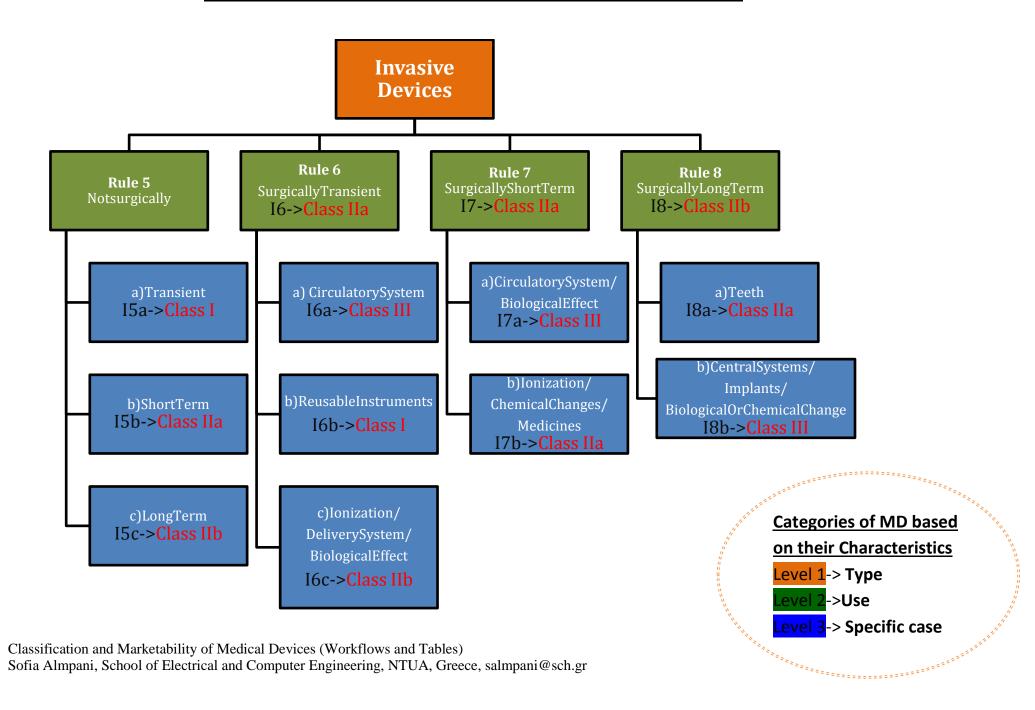
Classification and marketability of Medical Devices (1)



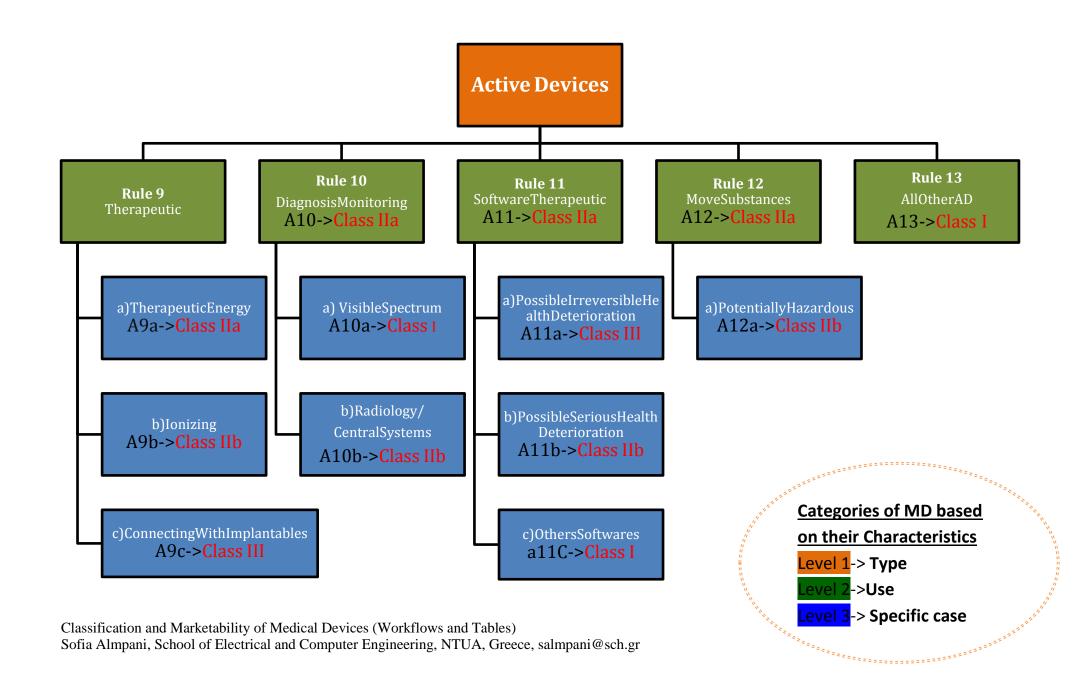
Classification and marketability of Medical Devices (2)



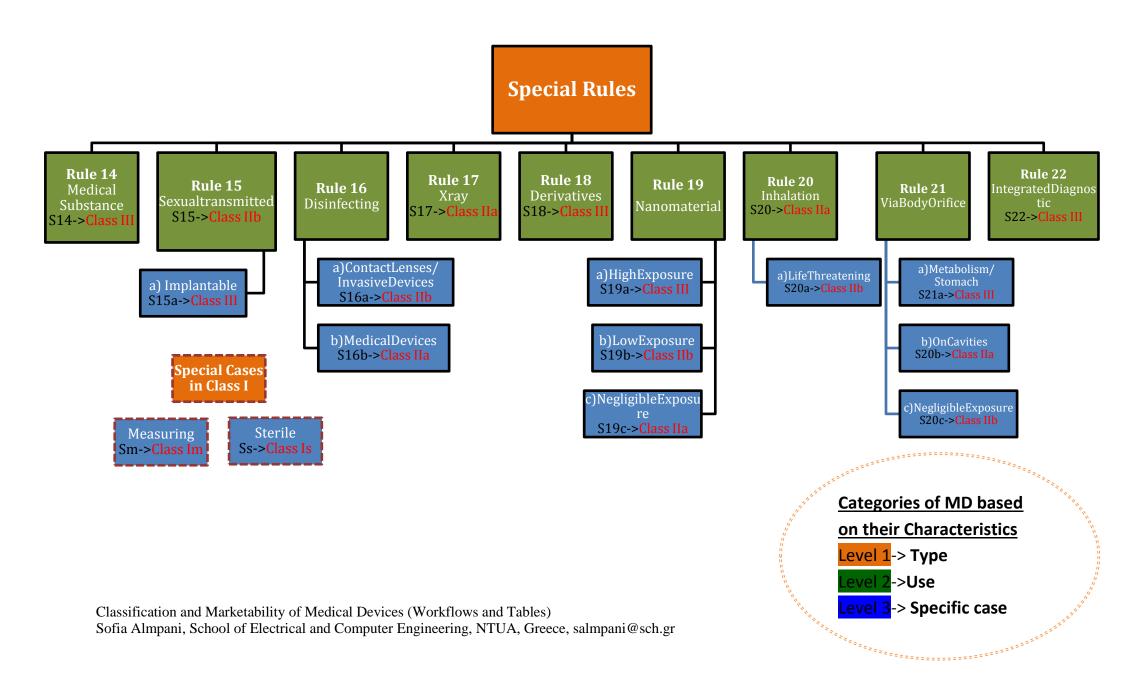
Classification and marketability of Medical Devices (3)



Classification and marketability of Medical Devices (4)



Classification and marketability of Medical Devices (5)



Classification and marketability of Medical Devices (6) Marketable For Manufacturer's **Declaration of Conformity** the Device m following five requirements must be fulfilled: Workflow for CE marking 1. Conformity Assessment & Technical File of the Medical Device - Annex VII 2. Manufacturer appointing a European **HasCEwithNBN** Authorized Representative (EAR) as in 93/42/EEC, Article 1 parag.2 3a. European Competent Authorities (ECA) as in 93/42/EEC, Article 14 for Class I DeclarationOfConformity 3b. Quality Assurance from Notified Body for Classes IIa.IIb.III 4a. Notified body Involvement for Classes Im, Is DeclarationOf Declaration Declaration Declaration Annex V, Article 3 Parag.1 ConformityIn OfConformityIn OfConformityIn OfConformityIn 4b. Type examination from NB for Classes IIb,III -Class IIb Clas IIa Annex III 5. Design Dossier Certificate in Full Quality Class I Conformity Conformity Class Im Class Is Assurance for Class III Assesment Assesment Conformity **AppointingA App**ointingA Assesment nEAR **nEAR** AppointingA ņΕΑŖ egisterW1th QualityAssurance QualityAssurance TheECA Production Production **FullOuality** Metrological FullQuality Sterile Testing Testing Requirements Conditions DesignDossier Design:Verif Design:Verif Manufacture:Yes Certificate Manufacture:Verif Design:Yes Manufacture:Ve Manufacture:Yes rif Production Inspection Production Quality Quality Inspection Quality Quality Design:No Design:No Manufacture:No Manufacture:Yes Design:No Design:No Classification and Marketability of Medical Devices (Workflows and Tables) Manufacture:Yes Manufacture:No

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Classification and marketability of Medical Devices (7)

Medical Devices' Facts (codes1) for each category													
Non-Inva	sive Devices	Invasive Devices			Active Devices					Devices with Special Rules			
Category	Fact	Category	Fact	Category	Fact	Category	Fact	Category	Fact	Category	Fact	Category	Fact
N1	MDN1214	I5a	DeviceR5a	I7a	MDA0101- ST	A9a	MDA0302	A11c	MDA0315c	S14	MDS1001	S19b	MDS1007b
N2a	MDN1202a	I5b	DeviceR5b		MDA0104b- ST	A9b	MDA0301	A12	MDA0306	S15	MDN1210	S19c	MDS1007c
N2b	MDN1202b	I5c	DeviceR5c	17b	MDA0104- ST	A9c	MDS1009	A12a	MDA0306a	S15a	MDN1210a	S20	DeviceR20
N2c	MDN1202c	16	MDA01		MDA0104a- ST	A10	MDA02	A13	MDA0318	S16	MDN1211	S20a	DeviceR20a
N3a	DeviceR3a	I6a	MDA0101		MDA0102- ST	A10a	MDA0202			\$160	MDA0317	S21a	MDN1213a
N3b	DeviceR3b	I6b	MDS1006	18	MDN11	A10b	MDA0201			S16a	MDA0317a	S21b	MDN1213b
N3c	MDN1212	I6c	MDA0104	I8a	MDN1103	Alub	MDA0204			S17	DeviceR17	S21c	MDN1213c
N4a	MDN1204a		MDA0104a		MDN1101 MDB1102	A11	MDA0315			S18	MDS1002	S22	DeviceR22
N4b	MDN1204b		MDA0102	I8b		A11a	MDA0315a				MDS1002	Ss	MDS1005
N4c	MDN1204c	17	MDA01-ST		MDN1104	A11b	MDA0315b			S19a	MDS1007a	Sm	MDS1010

Categories in each Class:

Class I: N1, N4a, I5a, I6b, A10a, A11c, A13 (Class Is: Ss/Class Im: Sm)

Class IIa: N2a, N2b, N3b, N4c, I5b, I6, I7, I8a, A9a, A10, A11, A12, S16b, S17, S19a, S20, S21b Class IIb: N2c, N3a, N4b, I5c, I6c, I7a, I8, A9b, A10b, A11b, A12a, S15, S16a, S19b, S20a, S21c

Class III: N3c, I6a, I7b, I8b, A9c, A11a, S14, S15a, S18, S19a, S21a, S22

¹ Retrieved from: http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R2185&qid=1517955018255&from=en In cases where the codes don't describe specifically a category other (random) coding is applied (black color). In cases where more than one category belongs in the same code, letters *a,b,c*, and *ST* are used.

Classification and marketability of Medical Devices (8)

Marketable and Non-Marketable Devices in each class (randomly)									
Class	Marketable: Yes	Marketable: No	Class	Marketable: Yes	Marketable: No				
Class I	MDN1214 MDA0202 MDA0318 DeviceR5a	MDN1204a MDS1006 MDA0315c DeviceR20	Class IIb	DeviceR3a DeviceR5c, MDA0104 MDA0101-ST MDA0104b-ST MDN11 MDA0201 MDA0315b MDN1210	MDN1202c, MDN1204b, MDA0102 MDA0301 MDA0204 MDA0306a MDN1211 MDA0317 MDN1213				
Class Is	MDS1005			MDS1007b	MDA0104a				
Class Im	MDS1010								
Class IIa	MDN1202a MDN1202b MDN1204c MDA01-ST MDN1103 MDA02 MDA0306 MDA0317a DeviceR17	DeviceR3b DeviceR5b MDA01, MDA0302 MDA0315 MDS1007c DeviceR20a MDN1213a MDN1213b MDN1213c DeviceR22	Class III	MDN1212, MDA0104-ST MDN1102 MDS1009 MDA0315a MDS1001	MDA0101, MDA0104a-ST MDA0102-ST MDN1101 MDN1104 MDN1210a MDS1002 MDS1003 MDS1007a				