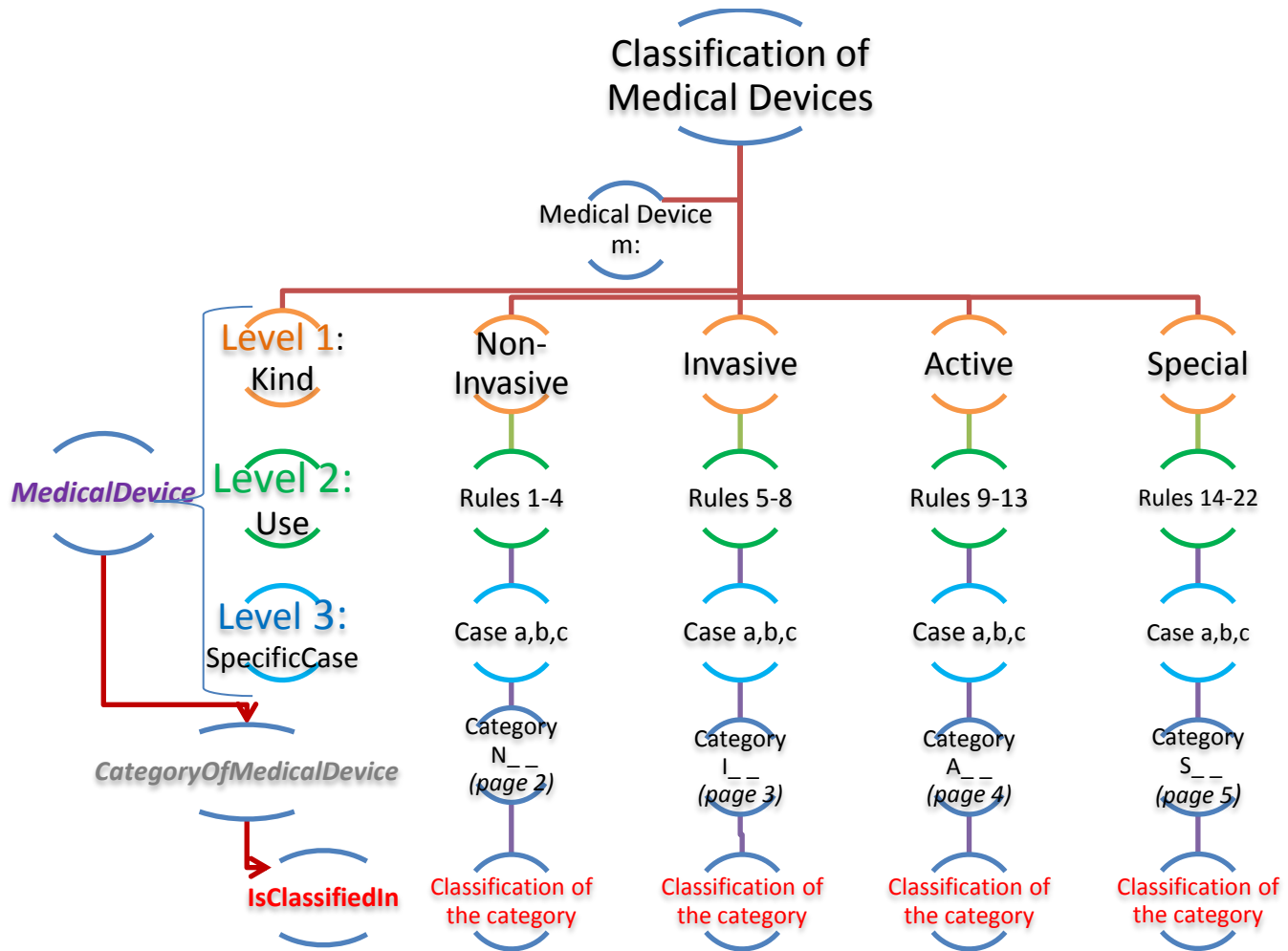
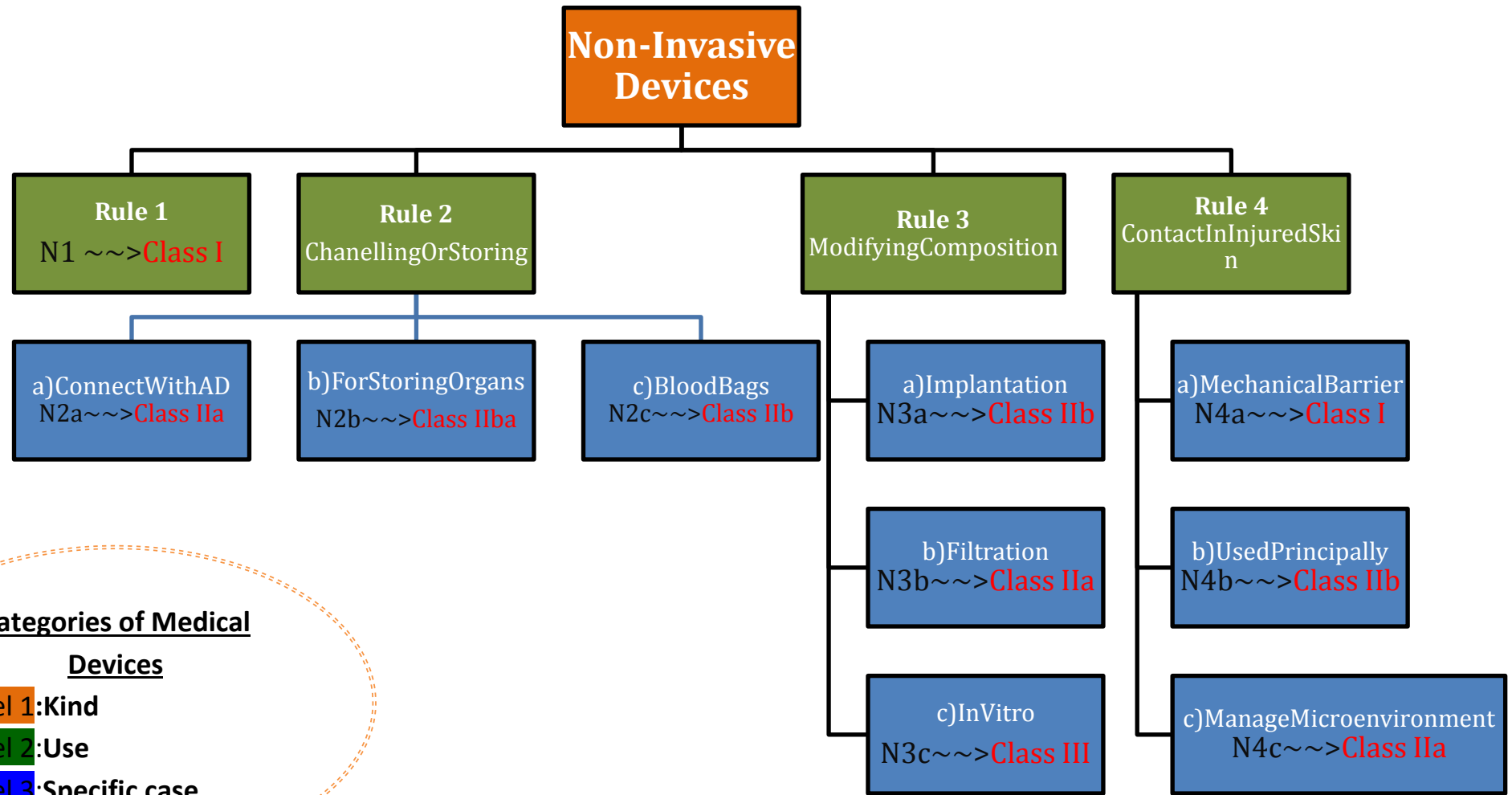


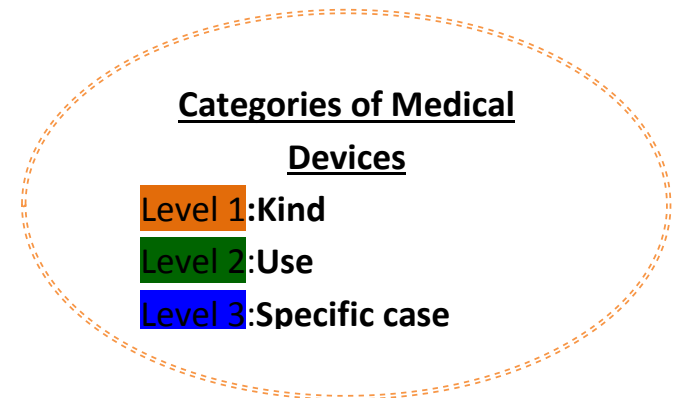
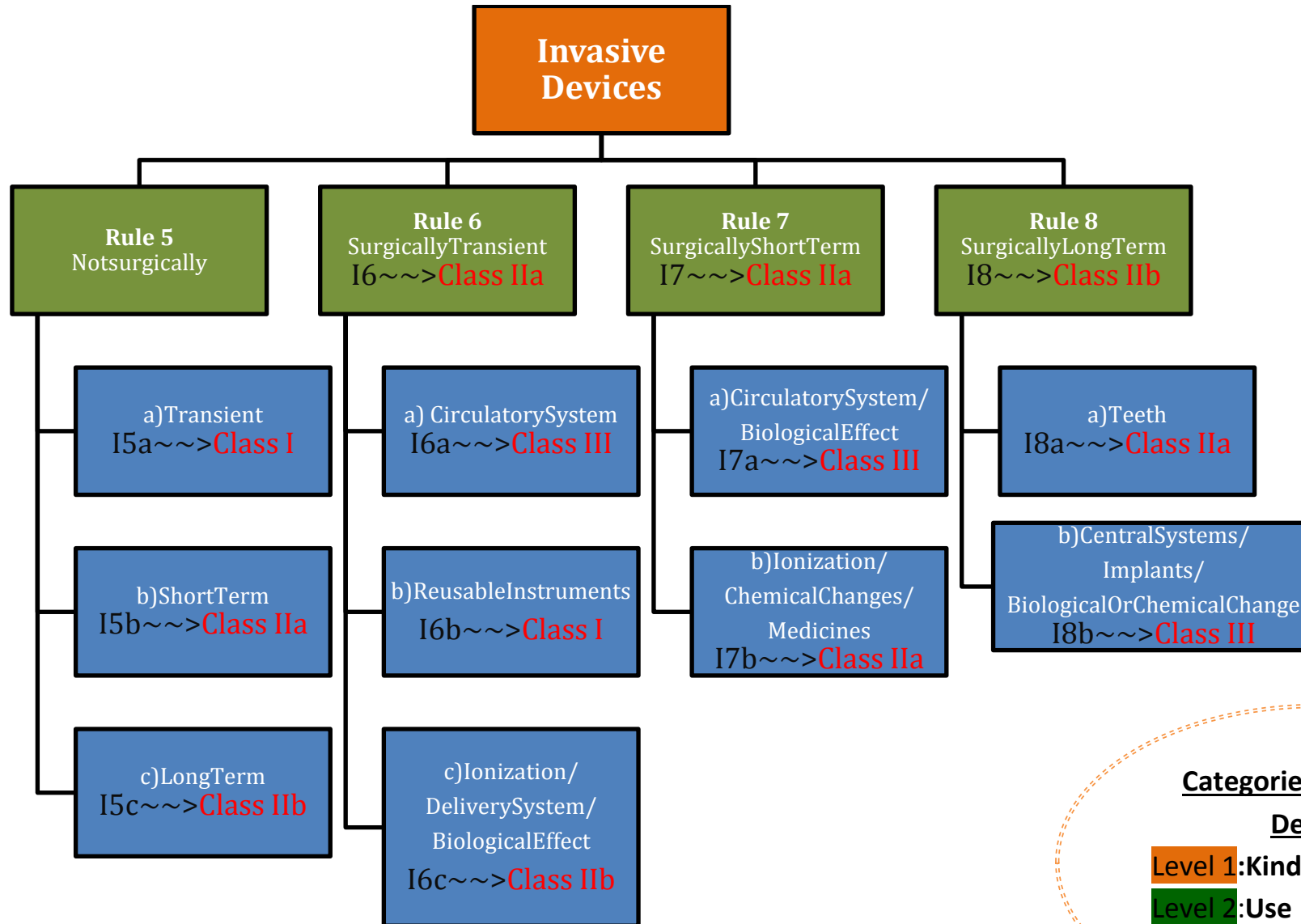
Classification and marketability of Medical Devices (1)



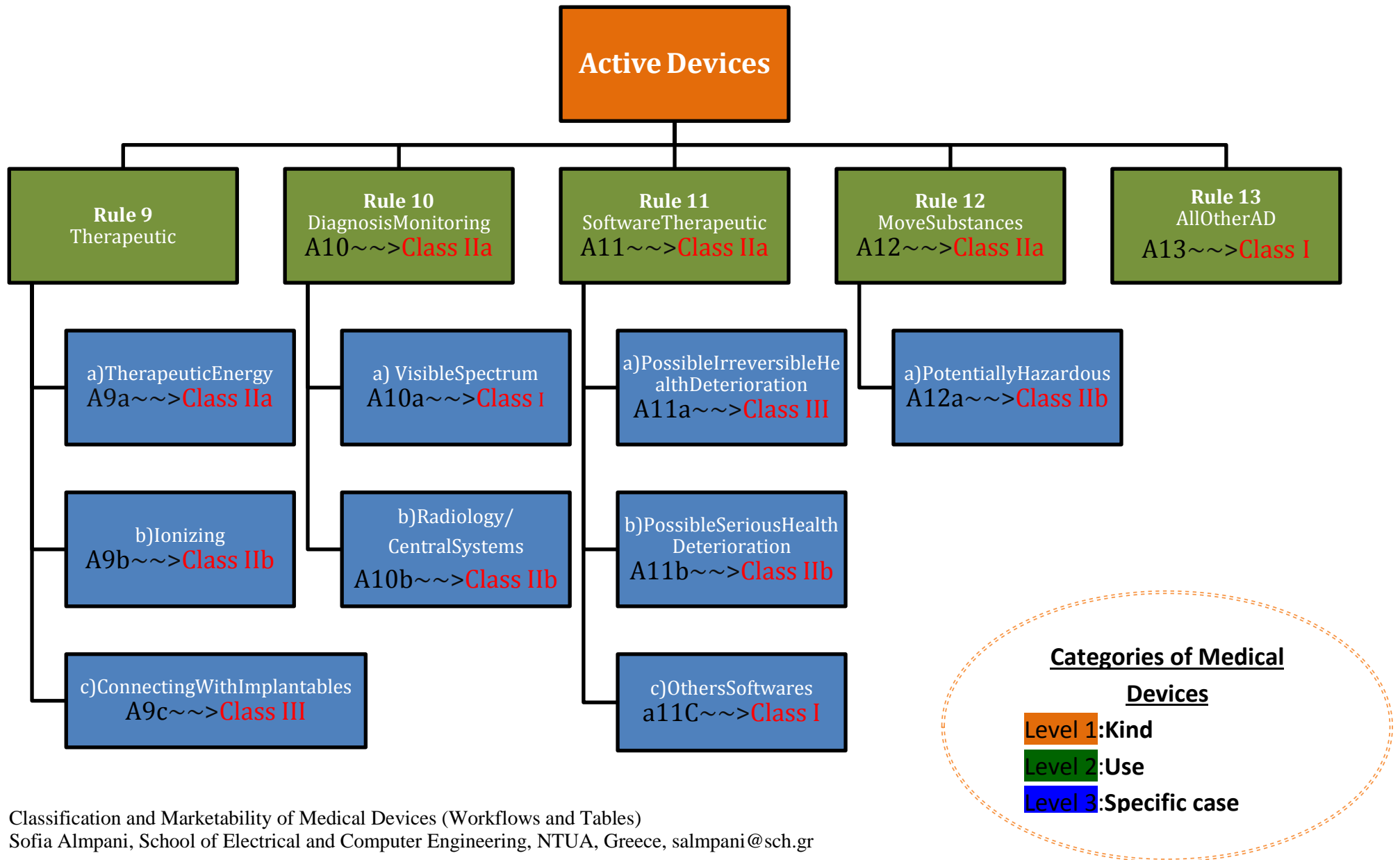
Classification and marketability of Medical Devices (2)



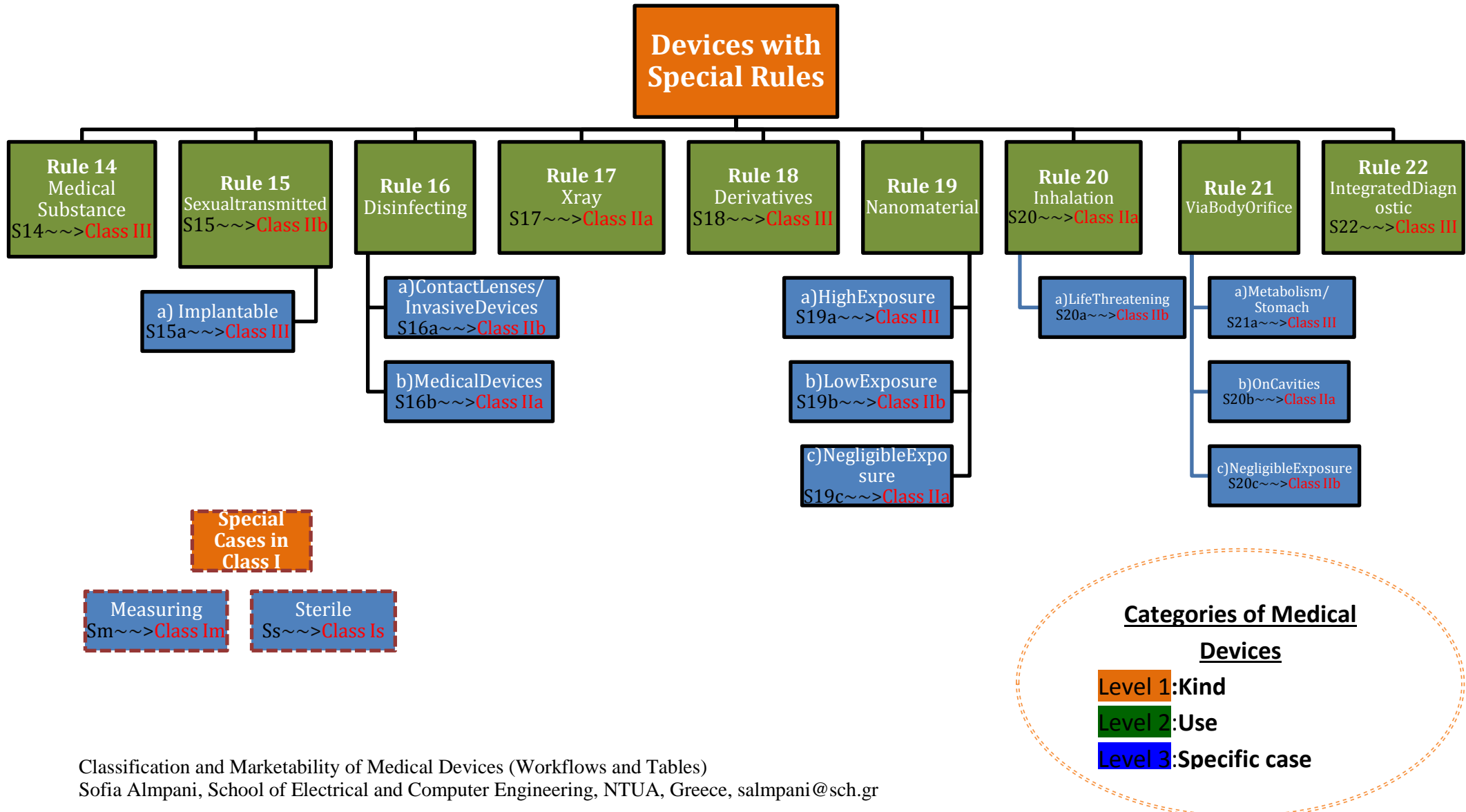
Classification and marketability of Medical Devices (3)



Classification and marketability of Medical Devices (4)

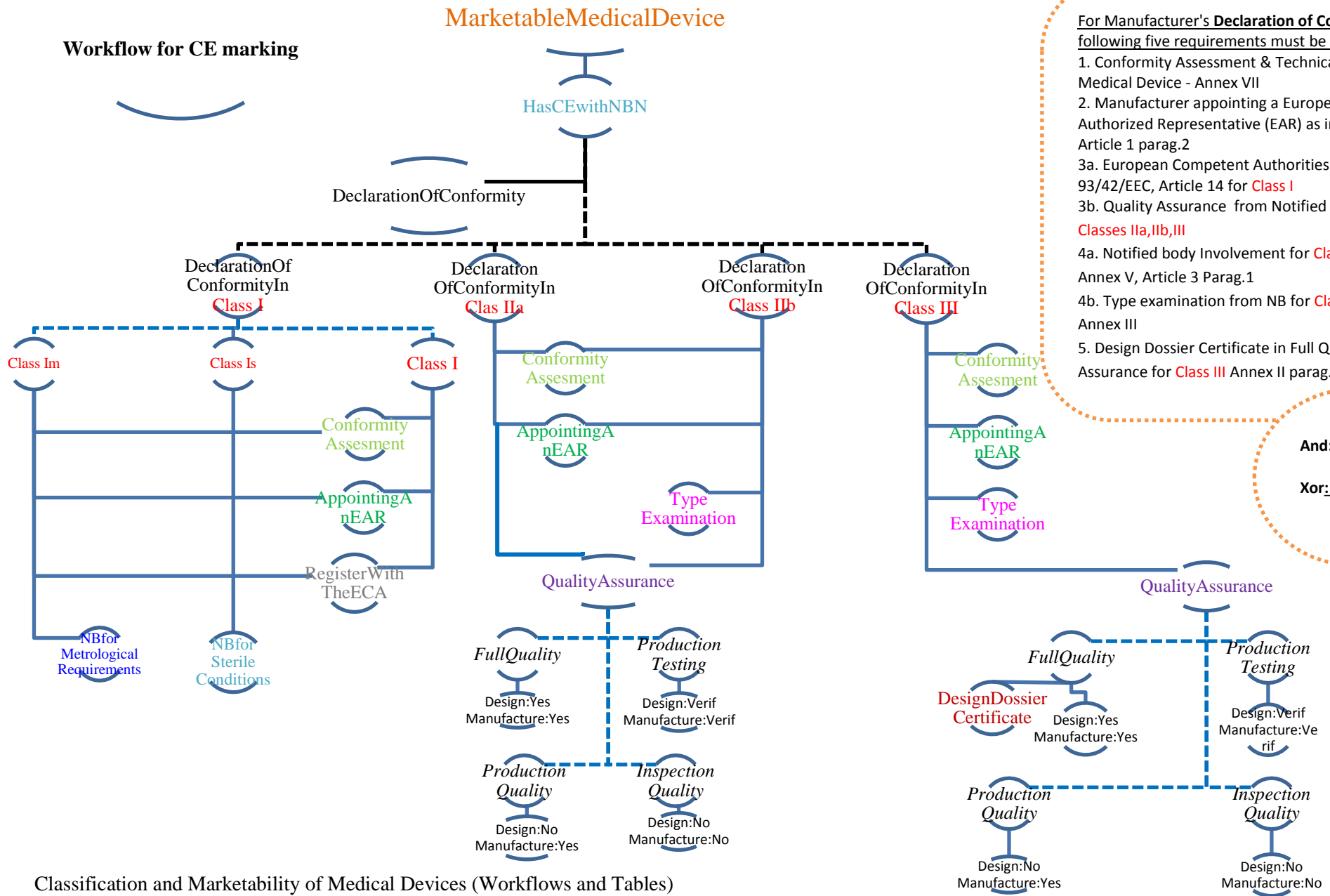


Classification and marketability of Medical Devices (5)



Classification and marketability of Medical Devices (6)

Workflow for CE marking



- For Manufacturer's **Declaration of Conformity** the following five requirements must be fulfilled:
1. Conformity Assessment & Technical File of the Medical Device - Annex VII
 2. Manufacturer appointing a European 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**
 - 3b. Quality Assurance from Notified Body for **Classes IIa,IIb,III**
 - 4a. Notified body Involvement for **Classes Im, Is** Annex V, Article 3 Parag.1
 - 4b. Type examination from NB for **Classes IIb,III** - Annex III
 5. Design Dossier Certificate in Full Quality Assurance for **Class III** Annex II parag.4

Classification and marketability of Medical Devices (7)

Medical Devices' Facts (codes¹) for each category

Non-Invasive 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	I7b	MDA0104-ST	A9c	MDS1009	A12a	MDA0306a	S15a	MDN1210a	S20	DeviceR20
N2c	MDN1202c	I6	MDA01		MDA0104a-ST	A10	MDA02	A13	MDA0318	S16	MDN1211	S20a	DeviceR20a
N3a	DeviceR3a	I6a	MDA0101		MDA0102-ST	A10a	MDA0202			S16a		MDA0317	S21a
N3b	DeviceR3b	I6b	MDS1006	I8	MDN11	A10b	MDA0201				MDA0317a	S21b	MDN1213b
N3c	MDN1212	I6c	MDA0104	I8a	MDN1103		MDA0204			S17	DeviceR17	S21c	MDN1213c
N4a	MDN1204a		MDA0104a	I8b	MDN1101	A11	MDA0315			S18	MDS1002	S22	DeviceR22
N4b	MDN1204b		MDA0102		MDB1102	A11a	MDA0315a				MDS1002	Ss	MDS1005
N4c	MDN1204c	I7	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 Medical Devices in each class (<i>randomly</i>)					
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 MDS1007b	MDN1202c, MDN1204b, MDA0102 MDA0301 MDA0204 MDA0306a MDN1211 MDA0317 MDN1213 MDA0104a
Class Is	<i>MDS1005</i>				
Class Im	<i>MDS1010</i>				
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 MDS1009 MDA0315a MDN1101 MDS1001	MDA0101, MDA0104a-ST MDA0102-ST MDN1104 MDN1210a MDS1002 MDS1003 MDS1007a MDN1102