Classification and marketability of Medical Devices (1)

Classification of Medical Devices

Medical Device m:

Level 1: Kind
- Non-Invasive
  - Rules 1-4
  - Case a,b,c
  - Category N_ _ (page 3)

Level 2: Use
- Invasive
  - Rules 5-8
  - Case a,b,c
  - Category I_ _ (page 3)

Level 3: Specific Case
- Active
  - Rules 9-13
  - Case a,b,c
  - Category A_ _ (page 4)

- Special
  - Rules 14-22
  - Case a,b,c
  - Category S_ _ (page 5)

Is Classified In

CategoryOfMedicalDevice

Classification of the category

Naming of CategoryOfMedicalDevice
ex. A10b from the Characteristics of MedicalDevice:
- Level 1: A: Active
- Level 2: 10: Rule 10
- Level 3: b: case b

Classification and Marketability of Medical Devices (Workflows and Tables)
Sofia Almpani, School of Electrical and Computer Engineering, NTUA, Greece, salmpani@sch.gr
Classification and marketability of Medical Devices (2)

Non-Invasive Devices

Rule 1
N1 ➔ Class I
  a) ConnectWithAD
     N2a ➔ Class IIa

Rule 2
ChanellingOrStoring
  b) ForStoringOrgans
     N2b ➔ Class IIa
  c) BloodBags
     N2c ➔ Class IIb

Rule 3
ModifyingComposition
  a) Implantation
     N3a ➔ Class IIb
  b) Filtration
     N3b ➔ Class IIa
  c) InVitro
     N3c ➔ Class III

Rule 4
ContactInInjuredSkin
  a) MechanicalBarrier
     N4a ➔ Class I
  b) UsedPrincipally
     N4b ➔ Class IIb
  c) ManageMicroenvironment
     N4c ➔ Class IIa

Categories of Medical Devices
Level 1: Kind
Level 2: Use
Level 3: Specific case

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Classification and marketability of Medical Devices (3)

Invasive Devices

Rule 5
Notsurgically

- a) Transient
  - Rule 5a
  - Class I

- b) ShortTerm
  - Rule 5b
  - Class IIa

- c) LongTerm
  - Rule 5c
  - Class IIb

Rule 6
SurgicallyTransient

- a) CirculatorySystem
  - Rule 6a
  - Class III

- b) ReusableInstruments
  - Rule 6b
  - Class I

Rule 7
SurgicallyShortTerm

- a) CirculatorySystem / BiologicalEffect
  - Rule 7a
  - Class III

- b) Ionization / ChemicalChanges / Medicines
  - Rule 7b
  - Class IIa

Rule 8
SurgicallyLongTerm

- a) Teeth
  - Rule 8a
  - Class IIa

- b) CentralSystems / Implants / BiologicalOrChemicalChange
  - Rule 8b
  - Class III

Categories of Medical Devices

Level 1: Kind
Level 2: Use
Level 3: Specific case

Classification and Marketability of Medical Devices (Workflows and Tables)
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Classification and marketability of Medical Devices (4)

Active Devices

Rule 9
Therapeutic
- a) Therapeutic Energy A9a ~> Class IIa
- b) Ionizing A9b ~> Class IIb
- c) Connecting With Implantables A9c ~> Class III

Rule 10
Diagnosis Monitoring A10 ~> Class IIa
- a) Visible Spectrum A10a ~> Class I
- b) Radiology/ Central Systems A10b ~> Class IIb

Rule 11
Software Therapeutic A11 ~> Class IIa
- a) Possible Irreversible Health Deterioration A11a ~> Class III
- b) Possible Serious Health Deterioration A11b ~> Class IIb
- c) Others Softwares A11c ~> Class I

Rule 12
Move Substances A12 ~> Class IIa
- a) Potentially Hazardous A12a ~> Class IIb

Rule 13
All Other AD A13 ~> Class I

Categories of Medical Devices

Level 1: Kind
Level 2: Use
Level 3: Specific case
Classification and Marketability of Medical Devices (5)

Sofia Almpani, School of Electrical and Computer Engineering, NTUA, Greece, salmpani@sch.gr

Classification and marketability of Medical Devices

Rules:
- Rule 14: Medical Substance
  - Subrule 14a: Implantable
    - S14a ~> Class III
- Rule 15: Sexual transmitted
  - Subrule 15a: Implantable
    - S15a ~> Class III
  - Subrule 15b: Medical Devices
    - S15b ~> Class IIb
- Rule 16: Disinfecting
  - a) Contact Lenses/Invasive Devices
    - S16a ~> Class IIb
  - b) Medical Devices
    - S16b ~> Class IIa
- Rule 17: X-ray
  - S17 ~> Class IIa
- Rule 18: Derivatives
  - a) Contact Lenses/Invasive Devices
    - S18a ~> Class IIb
  - b) Medical Devices
    - S18b ~> Class IIa
- Rule 19: Nanomaterial
  - a) High Exposure
    - S19a ~> Class III
  - b) Low Exposure
    - S19b ~> Class IIb
  - c) Negligible Exposure
    - S19c ~> Class IIa
- Rule 20: Inhalation
  - a) Life Threatening
    - S20a ~> Class IIb
  - b) Metabolism/Stomach
    - S20b ~> Class IIa
  - c) Negligible Exposure
    - S20c ~> Class IIb
- Rule 21: Via Body Orifice
  - a) Metabolism/Stomach
    - S21a ~> Class III
  - b) On Cavities
    - S21b ~> Class IIa
  - c) Negligible Exposure
    - S21c ~> Class IIb
- Rule 22: Integrated Diagnostic
  - S22 ~> Class III

Special Cases in Class I:
- Measuring
  - Sm ~> Class II
- Sterile
  - Ss ~> Class Is

Categories of Medical Devices

Level 1: Kind
Level 2: Use
Level 3: Specific case
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
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

Workflow for CE marking

Classifiable Medical Devices

HasCEwithNBN

DeclarationOfConformity

DeclarationOfConformityInClassI

DeclarationOfConformityInClassIIa

DeclarationOfConformityInClassIIb

DeclarationOfConformityInClassIII

ConformityAssessment

AppointingAnEAR

TypeExamination

QualityAssurance

FullQuality

ProductionTesting

ProductionQuality

InspectionQuality

Design:DossierCertificate

Design:Yes

Manufacture:Yes

Design:Yes

Manufacture:Verif

Design:No

Manufacture:Yes

Design:No

Manufacture:No

Design:No

Manufacture:Yes

Design:No

Manufacture:No

Classification and Marketability of Medical Devices (Workflows and Tables)
Sofia Almpani, School of Electrical and Computer Engineering, NTUA, Greece, salmpani@sch.gr
## Classification and Marketability of Medical Devices

### Medical Devices’ Facts (codes) for each category

<table>
<thead>
<tr>
<th>Category</th>
<th>Fact</th>
<th>Category</th>
<th>Fact</th>
<th>Category</th>
<th>Fact</th>
<th>Category</th>
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<td>DeviceR5a</td>
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<td>DeviceR5b</td>
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<td>I8</td>
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<td>MDA0104</td>
<td>I8a</td>
<td>MDN1103</td>
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<td>DeviceR17</td>
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<td>S19a</td>
<td>MDS1007a</td>
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</tr>
</tbody>
</table>

### 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, I7a, 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](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 (randomly)

<table>
<thead>
<tr>
<th>Class</th>
<th>Marketable: Yes</th>
<th>Marketable: No</th>
<th>Class</th>
<th>Marketable: Yes</th>
<th>Marketable: No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>MDN1214, MDA0202, MDA0318, DeviceR5a</td>
<td>MDN1204a, MDS1006, MDA0315c, DeviceR20</td>
<td>Class IIb</td>
<td>DeviceR3a, DeviceR5c, MDA0104, MDA0101-ST, MDA0104b-ST, MDN11, MDA0201, MDA0315b, MDN1210, MDS1007b</td>
<td>MDN1202c, MDA0102, MDA0301, MDA0204, MDA0306a, MDN1211, MDA0317, MDN1213, MDA0104a</td>
</tr>
<tr>
<td>Class Is</td>
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<td></td>
<td>Class IIa</td>
<td>MDA012a, MDA0202, MDA01204c, MDA01-ST, MDN1103, MDA02, MDA0306, MDA0317a, DeviceR17</td>
<td>DeviceR3b, MDA01, MDA0302, MDA0315, MDS1007c, DeviceR20a, MDN1213a, MDN1213b, MDN1213c, DeviceR22</td>
</tr>
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<td>Class Im</td>
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<td>Class III</td>
<td>MDN1212, MDA0104-ST, MDS1009, MDA0315a, MDN1101, MDS1001</td>
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</tr>
</tbody>
</table>

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