A Rule-Based Model for Compliance of Medical Devices Applied to the European Market

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Outline

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Introduction

- The **Regulation (EU) 2017/745** of the European Parliament and of the Council of 5 April 2017 on medical devices presents a framework of risk-based classification, leading to risk-appropriate conformity assessment procedures.
- Still in a trial period.
- In the medical domain there is an increasing interest in AI and computational decision-making approaches.
- Legal-AI models are often rule-based.
- This rule-based system is an initial attempt to develop a computational rule format of the EU Regulation 2017/745.
- A computational guideline to assist stakeholders of medical devices.

Outline

Regulation (EU) 2017/745 (1)

Classification criteria: Regulation (EU) 2017/745 contains 22 rules for the following four classes:

- **Class I** - Low risk devices[1], e.g. bandages, stethoscopes.
- **Class IIa** - Low-to-medium risk devices, e.g. hearing-aids.
- **Class IIb** - Medium-to-high risk devices, e.g. ventilators.
- **Class III** - High risk devices, e.g. prosthetic heart valves.

CE marking: A declaration from the manufacturer that the device complies with the essential requirements of the relevant European legislation.

[1] Special cases: *Class Is* for sterile and *Class Im* for measuring function.

Regulation (EU) 2017/745 (2)

The class-based requirements for the **Declaration of Conformity**:

- Conformity Assessment & Technical File of the Medical Device.
- Appointing a European Authorized Representative (EAR).
- European Competent Authorities (ECA), for **Class I**.
- Notified Body Involvement for **Classes Im, Is**.
- Quality Assurance from Notified Body for **Classes IIa, IIb, III**.
- Type examination from a Notified Body (NB) for **Classes IIb, III**.
- Design Dossier Certificate in Full Quality Assurance for **Class III**.

Outline

PSOA RuleML Formalization

Positional-Slotted Object-Applicative (PSOA) RuleML:

- It combines object-centered and relational modeling in a unified language.
- It is suitable for expressing deductions by rules over enriched atoms.

Our formalization “Medical Devices Rules” consists of five parts:

1. The 22 classification rules of the regulation.
2. The medical devices categories in each class.
3. The marketability of medical devices according to the various conformity assessment options.
4. An explicit taxonomy of the medical devices.
5. Representative data (facts) of medical devices.

Classification Rules (1)

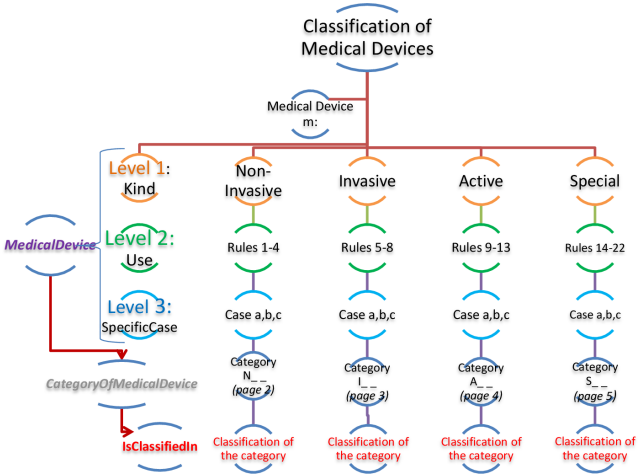

Figure: Visualization of PSOA RuleML decision model for classification rules.

Classification Rules (2)

- The **risk-based classification rules** of the regulation are linked to (informal) categories.
- One clause is used for each category, e.g. in Rule 4:

```
Rule 4: Devices in contact with injured skin.
Forall ?m (:CategoryOfMedicalDevice(?m :N4a) :-
  ?m#:MedicalDevice(:kind->:NonInvasive
                    :use->:ContactInjuredSkin
                    :specificCase->:MechanicalBarrier))
```

- The condition's predicate `:MedicalDevice` is a *frame atom*, where the hash infix # denotes *class membership* by typing an OID with its predicate, while the arrow infix, `->`, pairs each predicate-independent slot name with its filler.
- The predicate `:CategoryOfMedicalDevices` is a *relationship* that links the medical device with the category it pertains.

Categories and Classes

The aforementioned categories are connected with the class they reside in, forming an ‘Or’ branch (disjuction).

```
% Classification Grouping: Class I
  Forall ?m (:IsClassifiedIn(?m :I) :-
          Or(:CategoryOfMedicalDevice(?m :N1)
             :CategoryOfMedicalDevice(?m :N4a)
             :CategoryOfMedicalDevice(?m :I5a)
             :CategoryOfMedicalDevice(?m :I6b)
             :CategoryOfMedicalDevice(?m :A10a)
             :CategoryOfMedicalDevice(?m :A11c)
             :CategoryOfMedicalDevice(?m :A13)))
```

- The generated categories are indicated by three letters,
  e.g. :N4a,
  N: Non-Invasible device,
  4: Rule 4,
  a: specific case ‘a’, i.e. mechanical barrier.

Marketability of Medical Devices (1)

- All the different **conformity assessment** routes of each class for the CE marking and the implying **marketability** of medical devices are described.
- These routes outline the pre-marketability procedure.
- Requirements for Declaration of Conformity in Class I:

```
Forall ?m (:DeclarationOfConformity (?m) :-
  And(:IsClassifiedIn(?m :I)
      :RegisterWithTheECA(?m)
      :AppointingAnEAR(?m)
      :ConformityAssessment(:device->?m
                            :technicalFile->:Yes
                            :vigilanceSystem->:Yes
                            :harmonizedStandards->:No)))
```

Marketability of Medical Devices (2)

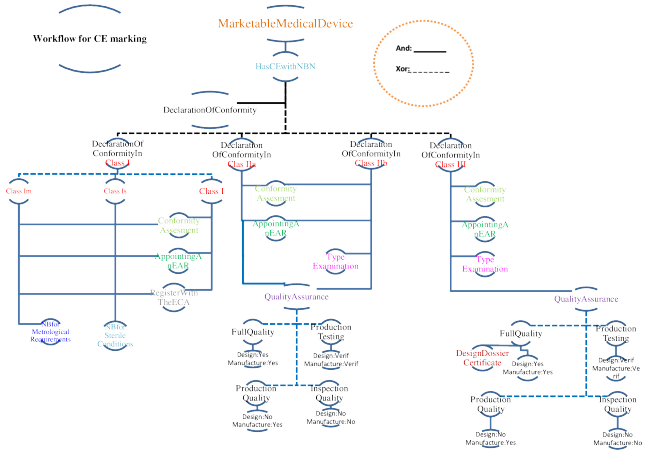

Figure: Marketability requirements for each class.

Taxonomy of Medical Devices (1)

- The Subclass relation (‘##’) (e.g., `:NonActiveInvasive##:MedicalDevices`) is used for building a variable-depth multi-layer **taxonomy**, containing more than 150 different medical device products.

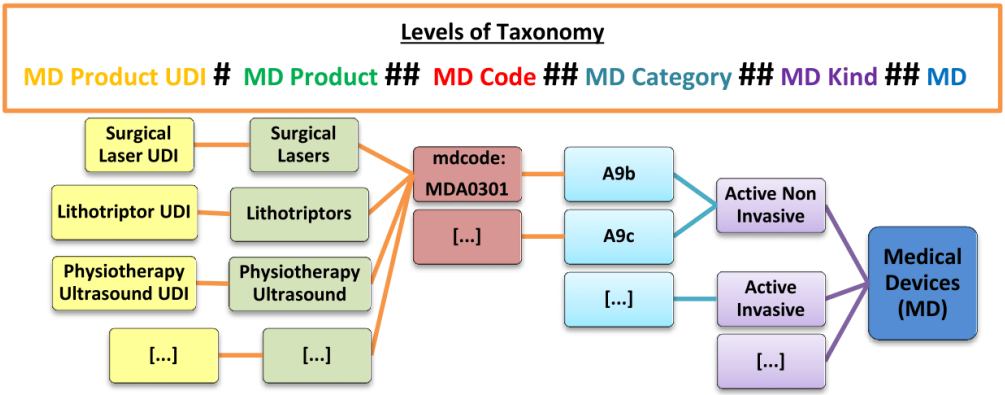

Figure: Visualization of a taxonomy example.

Taxonomy of Medical Devices (2)

Six-layered taxonomy:

- The five levels are ‘Subclass of’ `##`-levels.
- The last lower level is ‘Instance of’ `#`-level including individuals for each ‘Medical Device Product’ subclass with the suffix UDI.
- In PSOATransRun at least one level ‘Instance of’ `#` is required to allow retrieval.
- e.g., for `:AbsorbentPadsUDI`:

```
:NonActiveNonInvasive##:MedicalDevices
:N4a##:NonActiveNonInvasive
 mdcode:MDN1204a##:N4a
:AbsorbentPads##mdcode:MDN1204a
:AbsorbentPadsUDI#:AbsorbentPads
```

Representative Data (Facts) of Medical Devices

- **Data** for medical devices (Facts) were added in the KB.
- Medical devices facts were developed based on the list of codes (2017/2185) and the corresponding types of devices under Regulation (EU) 2017/745.

```
% Requirements of MDN1204a: Class I, 2Yes, No ECA

  mdcode:MDN1204a#:MedicalDevice(:kind->:NonInvasive
                                 :use->:ContactInjuredSkin
                                 :specificCase->:MechanicalBarrier)
  :AppointingAnEAR(mdcode:MDN1204a)
  :ConformityAssessment(:device->mdcode:MDN1204a
                        :technicalFile->:Yes
                        :vigilanceSystem->:Yes
                        :harmonizedStandards->:No)
```

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PSOATransRun (1)

- The Prolog instantiation of PSOATransRun, currently in version 1.3.2-a, is the reference implementation of PSOA RuleML.
- Representative queries to the KB have been posed and evaluated the answers obtained by PSOATransRun.
- PSOATransRun provided accurate answers in both typical and complex queries.
- Run-time performance: Instantaneous answers, even with queries with three different variables, e.g.:

```
And(:DeclarationOfConformity(?m)
    :QualityType(?m ?q)
    :IsClassifiedIn(?m ?c)).
```

PSOATransRun (2)

Limitations of the queries:

- Even though we can obtain all the medical devices that are in compliance with a specific marketability requirement, we cannot retrieve at once all non-compliant devices.
- We cannot retrieve all requirements to be fulfilled in order to establish the compliance of a device.
- In the taxonomy, we can ask about all upper classes only from a lower instance level (medical device product UDI), and in the top-to-bottom direction we can obtain only the instances of the lowest level, without the middle levels.

Representative Queries

```
> :IsClassifiedIn(mdcode:MDN1214 ?c)

?c=<http://psoa.ruleml.org/.../#I>

> :IsClassifiedIn(?m#:MedicalDevice(:use->:ModifyingComposition) :III)

?m=<http://eur-lex.europa.eu/legal-content/...#MDN1212>

> :MarketableMedicalDevice(mdcode:MDN1214)

Yes

> ?m#:N2b

?m=<http://psoa.ruleml.org/.../#TubesForBloodTransfusionUDI>
?m=<http://psoa.ruleml.org/.../#DevicesToStoreOrgansUDI>
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Conclusions

- We have demonstrated a formalization of a medical devices regulation as part of a logical KB leading to a computational decision model in PSOA RuleML.
- The resulting KB is capable of answering queries regarding the classification and marketabitily of medical devices aiming at compliance with the Regulation (EU) 2017/745.
- This has created an initial opportunity for decision support using this rule formalization via formal query, analysis, and proof, as well as permitting translation to other formalisms.

Future work and Proposed Longer-term Applications

- Extensions and improvements of the Medical Devices Rules KB following the adoption process of the Regulation.
- Post-marketability and/or clinical evaluation requirements.
- A generalized legal framework consisting of medical devices regulation combined with robotics-relevant regulations.
- Smart contracts applications: streamlining the secure tracking and management of medical devices and creating a transparent chain of medical records.
- “Healthcare as-a-service” business provided by IoT: all participating entities perform their role on pre-agreed contracts.

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Download the code:

http://psoa.ruleml.org/usecases/MedicalDevices/

Medical Devices Rules wiki:

https://wiki.ruleml.org/index.php/Medical_Devices_Rules