Computational Regulation of Medical Devices in PSOA RuleML

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Abstract. The registration and marketability of medical devices in Europe is governed by the Regulation (EU) 2017/745 and by guidelines published in terms thereof. This work focuses on formalizing the rules for risk-based classification of medical devices as well as the conformity assessment options for each class in Positional-Slotted Object-Applicative (PSOA) RuleML. We tested this open-source knowledge base by querying it in the open-source PSOATransRun system. The aim of this formalization is to create a computational guideline to assist stakeholders.

1 Introduction

In the medical domain there is an increasing interest in AI and computational decision-making approaches. To get maximum technology benefits for people in the medical device industry, it is required to proceed to solutions that integrate 'smart' services and innovative devices in compliance with existing legal frameworks, such as the Regulation (EU) 2017/745 [1] of medical devices. However, while logical reasoning on knowledge representations is rather well-understood, there are no established methods to convert a given medical legal text to an appropriate knowledge representation. For the conversion-reasoning tool chain it will be vital to obtain a high-enough conversion accuracy and to supplement machine-reasoning output with explanations that can be validated by humans.

Medical cases that combine ontologies with rule languages can be used as clinical guidelines [2] or for medical decision support [3]. Description logic-based ontology languages (e.g., OWL-DL) offer a precise semantics, but they can be computationally costly, and are mostly used to express ontology TBoxes about types of entities. Legal-AI models are often rule-based, where a legal text is represented by rules that can express legal definitions, exceptions, arguments, and deductions, and can provide explanations as audit trails of how a particular conclusion was proved.

Many health care procedures are supported by rule-based systems [4] such as for antibiotics prescription [4] and risk assessment of pressure ulcers [5]. In this work, Positional-Slotted Object-Applicative PSOA RuleML [6–8][4] is used for its simplicity and its suitability to express deductions by rules over enriched atoms. Since PSOA RuleML combines object-centered and relational modeling in a unified language, it supports object-relational data facts as well as transformation rules over them [6]. Details about PSOA RuleML syntax, psoa terms[5], and the query system PSOATransRun can be found in [8][6].

The main objectives of our work are a) to develop a computational rule format of the classification rules and the conformity assessment procedures for EU Regulation 2017/745, b) to supplement it with object-relational facts about medical devices to form a knowledge base, c) to build a separately reusable (and further extensible) explicit taxonomy, d) to test, with PSOATransRun queries [7], (for validation by humans), the accuracy of the developed computational model as well as its interpretability and reliability, and e) to create a computational guideline to assist regulators, manufacturers, importers, distributors and wholesalers of medical devices in the classification and registration of medical devices. To our knowledge, this is the first attempt to formalize, in a computational manner, a regulation of medical devices. Of course, this can only complement the classification and registration of medical devices by medical experts – it is an informative computational model of the regulation for stakeholders, rather than constituting expert knowledge.

The paper is organized as follows: Section 2 describes and evaluates the formalization of the medical devices regulation in PSOA RuleML, and Section 3 concludes the paper and outlines future directions.

2 Formalization of Medical Devices Rules in PSOA

The **Regulation (EU) 2017/745** [1] 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. Annex VII of the Regulation sets out the classification criteria with 22 rules for the following four classes:

Class I - Generally regarded as low risk[7], e.g. bandages, stethoscopes.
Class IIa - Generally regarded as low-to-medium risk devices, e.g. hearing-aids.
Class IIb - Generally regarded as medium-to-high risk, e.g. ventilators.
Class III - Generally regarded as high risk, e.g. prosthetic heart valves.

[4] PSOA RuleML generalizes F-logic, RIF-BLD, and POSL by a homogeneous integration of relationships and frames into psoa terms.
[5] We use the all-upper-case "PSOA" as a reference to the language and the all-lower-case "psoa" for its terms.
[6] See also the relevant RuleML wiki page `http://wiki.ruleml.org/index.php/PSOA_RuleML`
[7] Special cases: *Class Is* for sterile and *Class Im* for measuring function.

The **CE marking** on a medical device is a declaration from the manufacturer that the device complies with the essential requirements of the relevant European legislation. The appropriate conformity assessment procedures for the CE marking, depending on the product's class, can be viewed in Fig.2. Additionally, according to the Unique Device Identification (UDI) directive, medical devices' manufacturers are accountable to ensure complete traceability for their devices.

This use case[8] — Medical Devices Rules — illustrates how PSOA RuleML integrates the data and knowledge representation paradigms of *relationship atoms*[9] with those of *frame atoms*[10]. The formalization consists of five parts:

1. The 22 classification rules of the regulation.
2. The medical device 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.

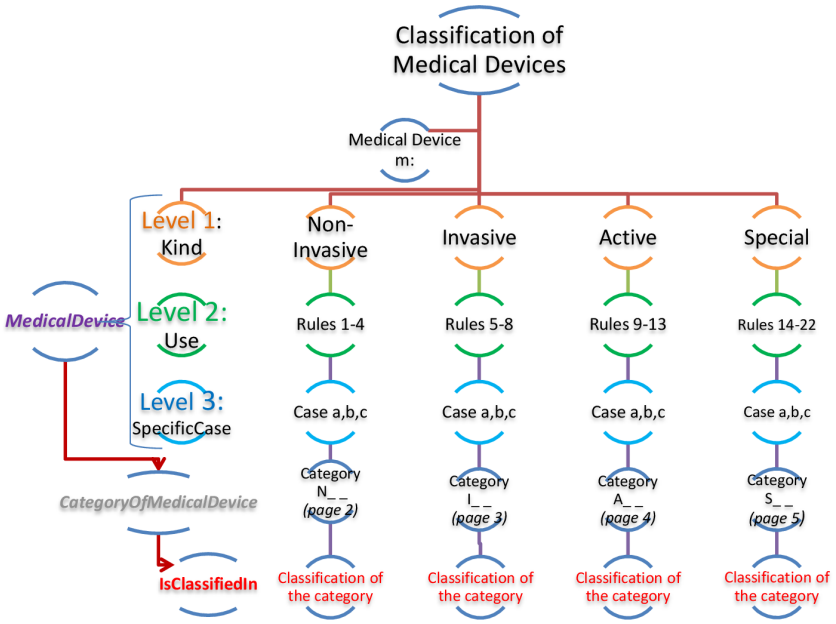

Fig. 1: Visualization of PSOA RuleML decision model for classification rules.

[8] Due to page limitations, the complete code source and queries of the Knowledge Base (KB) can be found in `http://psoa.ruleml.org/usecases/MedicalDevices/`

[9] Ordered tuple of positional arguments.

[10] A unique OID typed by a class and described by an unordered collection of slots.

In the first part, (informal) categories were created to formalize all the **risk-based classification rules** of the regulation. One clause is used for each rule, formed as the example[11] below,

```
% 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.

An exceptional case is the Rule 5, where time duration is also used for the categorization of the medical device into `:Transient`, `:Shortterm` or `:Longterm`. For this rule we used predicates with `math:` prefix as defined in the imported mathematics library `http://psoa.ruleml.org/lib/math.psoa`. They are shortcuts for external built-in calls in PSOA [8]. The specific case `:Shortterm` is described as follows:

```
% Rule 5 (Time period of usage: Short Term)
Forall ?m ?d (?m#:Time(:specificCase ->:ShortTerm) :-
          And(?m#:MedicalDevice(:duration->?d)
          math:lessEq(?d 30)
          math:greaterEq(?d 0.02)))
```

In the second part on the classification of medical devices, the aforementioned categories are connected with the class they reside in, forming an 'Or' branch (disjuction). The generated categories —55 in number— are indicated by three letters which denote the three levels of the categorization (see also Fig.1), e.g. :N4a, where **N** denotes a Non-Invasible device, 4 denotes Rule 4, and a denotes the specific case 'a', i.e. mechanical barrier. The categories in Class I are expressed in the following example:

```
%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)))
```

[11] It formalizes the sentence *"All non-invasive devices which come into contact with injured skin or mucous membrane are classified as: class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates"* [1, Chapter 3 (4.4) (a)]. The present work is restricted to the English version of the Regulation.

In the third part, 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. The post-marketability requirements are out of scope of the current work. In Class I, as described in the example below, all the conditions of the 'And' relation must be fulfilled to obtain the `:DeclarationOfConformity`.

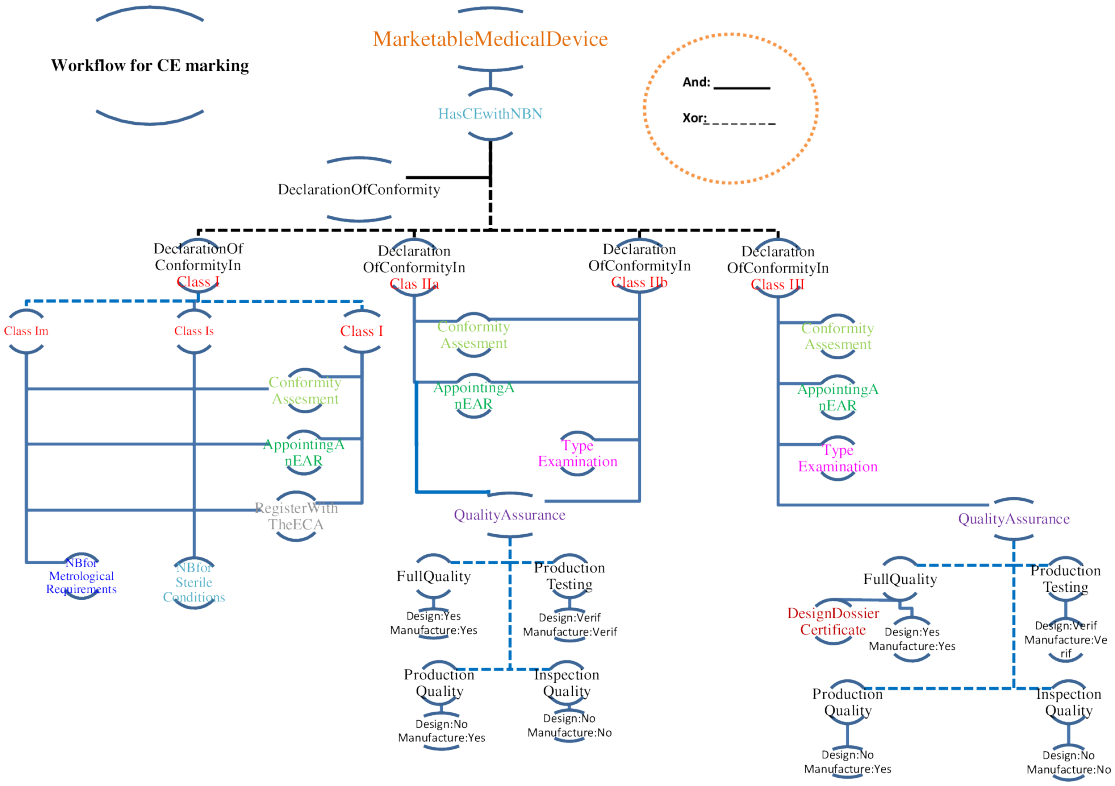

Fig. 2: Marketability requirements for each class.

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

The PSOA RuleML decision model for Conformity Assessment routes is visualized in Fig.2, with an object-relational 'And'-'Or' DAG ('And' branches are connected with straight lines, while 'Or' are connected with dashed lines). In 'Or' relations, only one choice from the possible options can be selected, either based on the

filler of the slot names, or on the different conditions of the 'And' clauses, so that only one route can be "fully invoked", causing near-deterministic behavior, e.g. for the Quality Assurance only one of the `:QualityType` can be "fully invoked".

In the fourth part, the Subclass relation (denoted in RIF and PSOA as '##') (e.g., `:NonActiveInvasive##:MedicalDevices`) is used for building a variable-depth multi-layer **taxonomy**, containing more than 150 different medical device products. The taxonomy consists of five levels as depicted in Figure 3 starting with the top class to the right and the sub classes to the left. The four levels

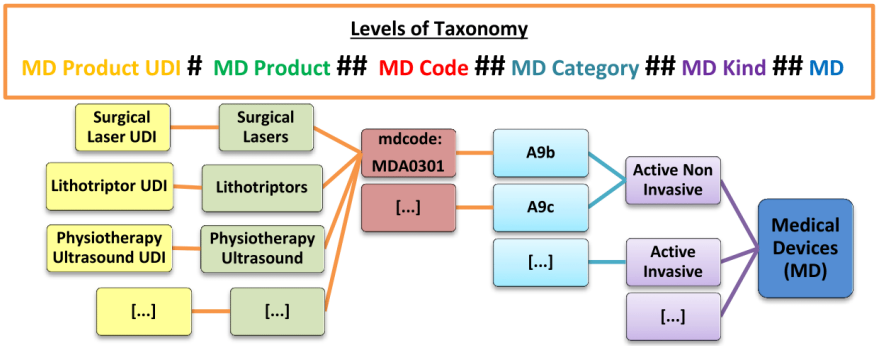

Fig. 3: Visualization of a taxonomy example.

are 'Subclass of' ##-levels, while the last level is 'Instance of' #-level including individuals for each 'Medical Device Product' subclass with the suffix UDI (e.g., `:NerveStimulatorsUDI#:NerveStimulators`). In PSOATransRun at least one level 'Instance of' ('witness' instances) is required to allow retrieval. The classes for `:NerveStimulatorsUDI` are described below:

```
:NonActiveInvasive##:MedicalDevices
:I8b##:NonActiveInvasive
 mdcode:MDN1102##:I8b
:NerveStimulators##mdcode:MDN1102
:NerveStimulatorsUDI#:NerveStimulators
```

In the last part, **Data** for specific medical devices (Facts) were added directly in the Medical Devices KB[12]. An example of a medical device fact is,

```
%Requirements of MDS1006:Class I 2Yes, No ECA
mdcode:MDS1006#:MedicalDevice(:kind->:Invasive :use->:SurgicallyTransient
:specificCase->:ReusableInstruments)
:AppointingAnEAR(mdcode:MDS1006)
:ConformityAssessment(:device->mdcode:MDS1006 :technicalFile->:Yes
:vigilanceSystem->:Yes :harmonizedStandards->:No)
```

[12] The medical devices facts are described with their specific characteristics and with their (randomly chosen) completed marketability requirements. The marketable medical devices in each class can be viewed in: `http://psoa.ruleml.org/usecases/MedicalDevices/ClassificationAndMarketability.pdf` (p.8).

The medical devices facts are covering all categories with qualitative slot-filler distinctions. Medical devices facts were developed based on the list of codes (2017/2185) [9] and the corresponding types of devices under Regulation (EU) 2017/745[13]. The predicates with the `mdcode:` prefix are used to describe the medical devices codes of the aforementioned directive.

To test the formalization, we have posed representative queries to the KB and evaluated the answers obtained by PSOATransRun[14]. The Prolog instantiation of PSOATransRun [7], currently in version 1.3.1, is the reference implementation of PSOA RuleML.

In both typical and complex queries the answers provided by PSOATransRun were accurate. One limitation for the queries in the taxonomy is that, even though we can ask about all upper classes of a specific level, we can obtain only the instances of the lowest level (without the intermediate levels). The run-time performance of PSOATransRun has also been evaluated. There was no noticeable delay in the retrieval (for the provided data set, which includes 55 categories in the KB and more than 150 examples of products in the taxonomy), even with queries with three different variables, e.g. `And (:DeclarationOfConformity(?m) :QualityType(?m ?q) :IsClassifiedIn(?m ?c))`.

The KB was additionally validated by a legal expert, corroborating our natural-language-to-logic mapping, as well as the expressiveness, interpretability, and accuracy of the formalization. Therefore, the KB can be considered accurate concerning the classification and marketability parts of the regulation.

3 Conclusions and Future Work

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 formalization resulted in an object-relational PSOA RuleML rulebase, which was supplemented by object-relational facts about medical devices, also in PSOA RuleML form. 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.

The goal of this formalization is to create a guideline to assist stakeholders in the classification and registration of medical devices. Because the regulation was published recently (still being in a trial period), extensions and improvements of the Medical Devices KB (including UDI/specific types of medical devices) should be of interest. Furthermore, post-marketability and/or clinical evaluation requirements can be added in the Medical Devices Rules.

[13] In cases where the codes don't describe specifically a category a random coding is applied (e.g.,`:DeviceR3a`), while in cases where more than one category belongs in the same code, letters *a,b,c* are used.

[14] Due to page limitations, detailed query examples for the Medical Devices Rules and answers from PSOATransRun can be found in `http://wiki.ruleml.org/index.php/Medical_Devices_Rules#Formalization_of_Medical_Devices_Rules_in_PSOA` `http://psoa.ruleml.org/usecases/MedicalDevices/`

Some proposed longer-term applications of this formalization can be a) the digital monitoring of (both pre- and post-marketing) traceability and management of medical devices with smart contracts by recording their UDIs on a blockchain, b) the potential creation of "Healthcare-as-a-service" IT systems, where numerous connected medical devices (e.g. devices with embedded software, wearables, medical assets that generate health data, etc.) are secured in a blockchain-based distributed network pursuant to the legislation, and/or c) an integration with further robotics-relevant regulations (e.g., wearables) to create a generalized legal framework.

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