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

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ABSTRACT

There is a growing producer and consumer interest in medical devices and the commensurate need for regulatory frameworks to ensure the quality of medical devices marketed locally and globally. This work focuses on formalizing the clauses enacted by Regulation (EU) 2017/745 for risk-based classification and class-based conformity assessment regarding marketability of medical devices. The resulting knowledge base (KB) represents clauses in Positional-Slotted Object-Applicative (PSOA) RuleML by integrating F-logic-like frames with Prolog-like relationships for atoms used as facts and in the conclusions and conditions of rules. Rules can apply polyadic functions, define polyadic relations, and augment conclusions with actions and conditions with events. The PSOA RuleML-implemented Medical Devices Rules KB was tested by querying in the open-source Java-implemented PSOATransRun system, which has provided a feedback loop for refinement and extension. This prototype can contribute to the licensing process of stakeholders and the registration of medical devices with a CE conformity mark.

KEYWORDS
CE marking, Classification, European Regulation 2017/745, Legal Compliance, Marketability, Medical Devices Rules, Ontologies, PSOA RuleML, PSOATransRun, Rules

INTRODUCTION

Based on the Global Medical Device Nomenclature Agency\(^1\), there are more than 2 million different types of medical devices on the world market, with this number growing constantly. The global medical device market is forecast to grow at a Compound Annual Growth Rate (CAGR) of 4.5% from 2018 to 2023 (Reportlinker, 2018) with an increasing market demand. It is expected that there will be a significant rise in remote monitoring, patient-managed diagnostic devices, smart wearable or implantable devices, e-health applications for smart phones, devices with nano-scale or 3D manufacturing, and other state-of-the-art technologies. This growth requires from companies to

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remain antagonistic in a global market and launch innovative medical devices products (EMBASE, 2015), which will need to be proven and verified according to the relevant regulations. Medical device companies are more than interested in learning how to deal with and automate the internal processes of pre-market approval paperwork and secure that regulatory submissions are thorough and on time (Ranise & Siswanto, 2017).

This increased need of computational medical records is usually supported by ontologies for taxonomic organization of information as well as legal-based rules for medical tests, procedures, and registrations, so that the quality of healthcare is secured and improved. Ontologies in the Semantic Web — represented with formal languages, such as Description Logics (DLs) — provide the representation for different types of medical knowledge, such as the OpenGalen ontology (Rector, Nowlan, & Consortium, 1994; Rector & Rogers, 2006) where methods were applied for restriction of medical terms to sensible classes. Similar techniques have been used to various medical nomenclature including the MeSH (Medical Subject Heading) (Šoumla, Golbreich, & Darmoni, 2004), the FMA (Foundational Model of Anatomy) (Rosse & Mejino, 2004), and the ICD10(International Classification of Diseases) (Heja, Surjan, Lukacsy, Pallinger, & Gergely, 2007). However, a demand has already been identified for expressive power beyond what is offered by DL-based ontology languages (Antoniou et al., 2005). Many health care procedures, such as inpatient clinical information systems (Cresswell & Sheikh, 2017), antibiotics prescription (Lezcano, Sicilia, & Rodríguez-Solano, 2010), and risk assessment of pressure ulcers (Rector & Rogers, 2006), are supported by computer aided decision making leading to increased interest in rule-based systems (Lezcano et al., 2010). In spite of existing theoretical issues of the complementary nature between ontology and rules languages, there is a need of Semantic Web Technologies for integrated formalisms that can provide advanced reasoning capabilities (Eiter, Ianni, Krenwallner, & Polleres, 2008), such as in SNOMED CT (Standardized Nomenclature of Medicine Clinical terms) (Navas et al., 2010) which proposed rules expressed in DLs for consistency checking of terms. Medical applications that combine ontologies with rule languages can be used, e.g., as clinical guidelines (Casteleiro & Diz, 2008; Chen, 2010) and for medical decision support (Djedidi, 2007), which can be subjects of privacy and regulatory compliance as well. Thus, in some applications, it can be practical to regulate compliance process by using formalized parts of applicable laws.

The complexity of regulations in healthcare domain (which are usually represented as moderately controlled natural-language text) makes it difficult for enterprises to design and develop effective compliance systems for their applications (Peifung, Lam & Sundaram, 2009). 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 (Holzinger, Biemann, Pattichis, & Kell, 2017). The length of the legal texts, the complexity of their acts, and the vagueness of their language make it complicated for business professionals to estimate whether they are compliance. This difficulty becomes even more important if programmers wish to develop and configure automated systems to help practitioners comply with applicable laws (Peifung, Lam & Sundaram, 2009). Medically relevant regulations have been subject of formalization in USA, e.g. FDAAA TrialsTracker (DeVito, Bacon, & Goldacre, 2018), a live informatics tool for FDA^2-compliance in clinical trials, in (Peifung E. Lam & Sundaram, 2009), an online prolog-based auditor, and, in (Maxwell & Antón, 2009), a production rule model, both of them for HIPAA^3-compliance in health information. This work is an initial attempt to formalize, in a computational manner, a European regulation of medical devices. EU Regulation of medical devices concerning the classification rules and the declaration of conformity procedures (thus, requiring both medical-classified and legal-based organization of
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