Research Article

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ExosCE: A legal-based computational system for compliance with exoskeletons' CE marking

<https://doi.org/10.1515/pjbr-2020-0026>

received November 24, 2019; accepted July 7, 2020

Abstract: Wearable robots are devices intended to improve the quality of users' life by augmenting, assisting, or substituting human functions. Exoskeletons are one of the most widespread types of wearable robots, currently used extensively in medical applications (and also for industrial, assistive, or military purposes), thus governed by regulations for medical devices and their conformity assessment. On top of that, manufacturers must also specify if their exoskeletons can be categorized as machines and, therefore, additionally apply a number of requirements mandated from machinery regulations. This work focuses on capturing both the abovementioned requirements enacted by the Medical Devices Directive 2017/745 and the Machinery Directive 2006/42 into a single framework. It formalizes into Rules the Conformity Assessment procedures regarding the marketability of exoskeletons indicated by the CE marking ("Conformité Européene"). These Rules, expressed in the Positional-Slotted Object-Applicative (PSOA) RuleML code, were complemented by representative Facts based on real-life cases of commercialized exoskeletons. Additional Exoskeletons Facts can be included by users from other forms (such as MS Excel) and translated into the PSOA RuleML code through the provided Python script. The open-source Exoskeletons' CE mark (ExosCE) Rules KB was tested by querying in the open-source PSOATransRun system. The ExosCE Rules prototype

can assist in the compliance process of stakeholders and in the registration of exoskeletons with a CE mark.

Keywords: wearable robots, exoskeletons, conformity assessment, CE marking, PSOA RuleML

1 Introduction

Wearable robots aim to significantly improve the quality of users' life by assisting, augmenting, or enhancing mobility and motion in various human movement applications and scenarios [1,2].

At the present time, robots' adoption is not widespread. However, studies indicate that this will gradually change [3], since robotic systems may bring benefits and conveniences to our society. Wearable robots may reinforce areas of applications that cover wide-ranging domains [2]. Some of the potential applications of wearable robots in health care are rehabilitation treatment for patients recovering from trauma, movement aids for disabled persons, support for an extended autonomous life of elderly, and decrease in repetitive tasks of care personnel [1]. Additionally, they can be used to decrease the burden in physically demanding jobs and reduce the work-related injuries, thus increasing the productivity and work quality in the industry [2].

There is a growing interest for producers and users in wearable robots [4]. Thus, it is essential not only to emphasize on developing prototypes and technologies for testing in research labs but also to have an explicit perspective on how this progress can genuinely influence the society [5]. According to this, focus should be on wearable robot market shaping, so that stakeholders (i.e., regulators, roboticists, manufacturers, etc.) are conscious of the legal matters that require attention [5,6]. This article outlines the international framework that is relevant in realizing new markets for these urgently needed technologies, mainly focusing on the reports by the European Parliament. In this regard, there is a need for a computational formalization of the existing regulation to promote the systematic use and ensure

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the quality of the procedure required in order to provide the emerging devices to the marketplace nationally or internationally.

The European Union (EU) has several EC Directives adopted as law, and two such directives are currently the most relevant to be applied for wearable robots, namely, the Machinery Directive 2006/42/EC (MD) [7] and the Medical Devices Directive 2017/745/EC (MDD) [8]. The MD applies to machines generally defined as devices with at least one moving part, containing actuators, control, and power circuits, while the MDD applies to any robot designed to meet a medical need and to be used for diagnostic and/or therapeutic purposes. The regulations directed by the MD and the MDD specify the requirements that manufacturers need to comply with in order to obtain a CE marking (abbreviation of French phrase “Conformité Européene”) to allow the commercialization of their device. Some devices – such as wearable robots – need to comply with some of the requirements of both regulations [9].

The vagueness, the length, and the complexity of legal texts make it difficult for the manufacturers to develop effective compliance systems for their devices and estimate whether they are in compliance [10]. While reasoning based on logic rules on knowledge representations is rather well understood, there are no specific and standard methods to translate a given legal text (which is usually represented as moderately controlled natural-language text) to a proper knowledge representation [11]. Various regulations have been the subject of computational formalization in the USA. The FDAAA TrialsTracker [12] is a live informatics tool for compliance with Food and Drug Administration (FDA) in clinical trials. For compliance with the Health Insurance Portability and Accountability Act in health information, a production rule model is presented in [13] and a Prolog-based auditor in [10].

With the current growth in rehabilitation and personal care robots, interest in wearable exoskeletons has been growing, which is caused by the demand for assistive technologies in general and specifically to respond to the concerns on the increasing aging population [14,15]. Exoskeletons are wearable robots that are fastened to the body of the consumers, extending their physical capabilities in a complementary or augmentary way. In the case of exoskeletons, complying with both medical device and machinery regulations could be required [3,9].

This article describes a novel attempt to formalize, in a computational manner, the exoskeleton-related parts of the European Directives. This study extends previous works concerning the formalization of MDD [16–18]. It

focalizes specifically in the case of exoskeletons as a type of medical device and incorporates the relevant requirements from the MD, regarding their safety and marketability. To the extent of our knowledge, there is no previous work regarding the development of a computational system for the CE marking compliance of exoskeletons. The Exoskeletons' CE marking (ExosCE) Rules' prototype can contribute to the effort of unifying the abovementioned legal frameworks to a computational format, as part of legal-informatics efforts. In this article, an example of an exoskeleton type is presented (Section 4) as an effort to formalize parts of the clauses enacted by the MDD and the MD in the positional-Slotted Object-Applicative (PSOA) RuleML.

One of the main benefits of ExosCE Rules is that it can aid in the licensing process of manufacturers to obtain the CE conformity mark. Actually, it can benefit exoskeletons' stakeholders variously, since it can assist them to comprehend the required steps and gain time from the labor-intensive procedures as well as to avoid failures and fines. Other problems that ExosCE attempts to facilitate is the communication gap between the technical and non-technical stakeholders to ease the interdisciplinary understanding between roboticists, medical, and legal experts. Moreover, it can contribute to the automation of conformity assessment checking for the CE marking with an audit rule-based system. The main objectives of our work are to:

- explore the exoskeleton-relevant regulatory framework and provide a brief review on the directives and the emerging international safety requirements,
- present an example case study on commercializing exoskeletons,
- develop a combined computational rule format and form a Knowledge Base of the core parts of the MDD 2017/745 and the MD 2006/42 realized with PSOA Rules and Facts about exoskeletons,
- create a user-friendly checklist for the Conformity Assessment requirements by using MS Excel and a Python script to automatically translate the checked requirements into a PSOA RuleML code,
- test with PSOATransRun queries the accuracy, interpretability, and reliability of the described computational model that allows its validation by humans, and
- create a basis for computational guidance, aiming to assist stakeholders in the compliance procedure of exoskeletons for the CE mark.

The generated prototype – ExosCE Rules – can only supplement the conformity assessment and the registration of exoskeletons by legal experts – it is an instructive

computational system of the related European regulations for stakeholders, rather than constituting expert knowledge.

The article is organized as follows: Section 2 presents an overview of the regulatory framework of Wearable Robots, and Section 3 highlights the main legal issues regarding exoskeletons. Section 4 describes the formalization of MDD and MD regulations in PSOA RuleML. Section 5 describes the user's interface, and Section 6 demonstrates queries and evaluates the results returned by PSOA-TransRun. Section 7 concludes the article. Appendix A provides representative fragments of the ExosCE Rules KB.

2 An overview of the regulatory framework of wearable robots

The growth of wearable robot market (it is expected to record a CAGR of 22.17% over the period 2020–2025¹) makes it essential to regulate critical aspects such as reliability, safety, and protection. The world of wearable robots is heterogeneous with wide diversification in potential risks of harm to the consumer. The close proximity between the wearable robot and the user exposes the latter to multiple risks that need extreme scrutiny [19]. Public trust in wearable robots needs effective and efficient regulations relying on a well-built legal and policy foundation as well as sound regulatory strategies [20]. This section provides an overview concerning the existing legal European framework and where the new wearable robots fit – mostly focusing on the lately adopted directives by the European Parliament and the relevant standards.

The EU Law does not contain explicit rules on robots, but there are EU legislations related to robotic devices, which are set in two basic directives: MD 2006/42/EC and MDD 2017/EC. The abovementioned directives specify the CE marking requirements that manufacturers need to comply with in order for their devices to be placed in the markets [6]. Notice that it is prevalent for exoskeletons to gain CE marking in the Europe before getting FDA's marking in the USA, as in the cases of ReWalk,² Ekso,³ HAL,⁴ and Rex.⁵

ReportLinker, "Medical device market report: trends, forecast and competitive analysis", December 2019, <https://www.reportlinker.com/p05380672>.

² <https://rewalk.com/>

³ <https://eksobionics.com>

⁴ <https://www.cyberdyne.jp/>

2.1 MD 2006/42/EC

The MD aims to support the design of machinery that is as safe as possible in line with the cutting-edge technological advances. This directive refers to machines mainly defined as devices with power circuits, actuators, control, and, at least, one moving part. It sets the basic Essential Health and Safety Requirements (EHSRs) that apply to all manufacturers who want their devices to be placed in the market. Compliance with the EHSRs can be achieved with the harmonized European standards.

Most robots (i.e., also wearable robots) have so far been categorized as machines, and therefore, the robot safety standards need to be compliant with this directive [21]. However, the harmonized standards published under the MD do not involve the combination of a machine and a wearable device. Consequently, standards and guidelines need improvement and updating to cover exoskeleton's technology [19]. An issue that is quite new in wearable robots regulated under the MD is the idea of intended contact between a user and a robot [22]. Although the majority of industrial robots are still detached from human, in physical-assistant robots – such as exoskeletons – physical contact is an important part of the intended task [22] (a requirement that was taken into consideration in the development of International Organization for Standardization (ISO) 13482 [23]).

2.2 MDD 2017/745/EC

The MDD refers to any device designed to meet a medical need and is used for diagnostic and/or therapeutic purposes. In this case, the product must be regulated as a medical device (under the MDD) rather than as a machine (under the MD). The new Regulation (EU) 2017/745 [8] of the European Parliament on medical devices presents a framework of risk-based classification leading to risk-appropriate CE market requirements. The classification criteria are described with 22 rules in the form of moderately controlled natural language. The rules are grouped based on the different types of devices, i.e., noninvasive, invasive, active, and medical devices with special rules (Annex VII of the Regulation). They categorize the devices into four classes: Class I is regarded as low-risk devices, e.g., bandages; Class IIa is regarded as low-to-medium-risk devices, e.g., hearing

⁵ <https://www.rexbionics.com/>

aids; Class IIb is regarded as medium-to-high-risk devices, e.g., ventilators; and Class III is regarded as high-risk devices, e.g., prosthetic heart valves.

The updated version of MDD that will be enforced after 2020 includes some critical changes, aiming to ensure that all medical devices in the market in the EU are safe and efficient [17]. The definition of medical devices is broadened, so that a wider set of products will now fall within the scope of the Regulation. Consequently, the definition of a medical device (see [8, Article 1 (2) (a)]) is extended from the definition in the previous regulation to include software (e.g., smart device apps), nanomaterials, devices not intended for medical purpose (e.g., wearable robots/technology), and other devices depicting the demands of state-of-the-art technologies [24,25]. The MDD also outlines that devices for which a manufacturer claims a non-medical purpose but their functions and risks are similar to medical devices should be covered by this Regulation. Moreover, the transparency and accountability of all suppliers in the medical device sector are enhanced, by creating Eudamed – a European Databank of medical devices [26] – and by requiring Unique Device Identifications (UDIs) for each device. UDIs can provide an audit trail of the device's progress through the supply chain (helping, e.g., to detect counterfeit devices). The market and postmarket surveillance is enhanced as well as the requirements for notified bodies. In addition, manufacturers must have at least one appropriately qualified person (European Authorized Representative) responsible for regulatory compliance.

2.3 Comparison of MDD and MD safety requirements

According to the MDD, medical devices that are also machinery shall meet the EHSRs of the MD. In Article 12 of MDD, it is outlined that

Devices which are also machinery within the meaning of point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council shall, where a hazard relevant under that under the Directive exists, also meet the essential health and safety requirements set out in Annex I to that Directive to the extent to which those requirements are more specific than the general safety and performance requirements set out in Chapter II of Annex I to this Regulation. [8]

According to this, manufacturers must specify whether their products can also be categorized as machines and thus comply with the MD as well. A detailed definition of what constitutes a machine is provided in the MD, which

can assist manufacturers to distinguish whether their device is also classified as a machine. The basic feature of a machine is the accessibility of the movable parts; thus, wearable robots and exoskeletons also fall into the category of machines.

EHSRs are applied for medical devices when the hazard is related and it is not covered by the essential requirements of the MDD or it is only partially covered. The requirements of machinery that can be considered applicable for medical devices that meet the definition of machinery – thus for exoskeletons as well – are shown in Figure 1.

This is very significant as the MD is dated since 2006 and does not take account of the updates concerning ISO 12100:2010 on safety machinery and ISO 13482:2014 on personal care robots [27]. In the case of exoskeletons, it is required to comply with both medical device and machinery regulations, depending on the application domain they are sold for, such as industrial, medical, or personal care [6]. Thus, if there are related hazards connected with the product's classification as a machine, manufacturers must assess the EHSRs in line with the provisions described in the MD.

The MD applies to various products. Annex I of the Directive enumerates about 50 EHSRs; a number of which can instantly be overlooked as they are obviously not relevant to medical devices. This leaves around 12 requirements that can be considered applicable, although the definite number of the requirements will differ depending on the product. Understanding all the EHSRs

Essential Health And Safety Requirements of MD 2006/42/EC that are applicable to Medical Devices	
Essential Health And Safety Requirements (EHSR)	
1.1.1 Definitions	
1.1.4. Lighting	
1.1.8 Seating	
1.2.2. Control devices	
1.5.4 Errors of fitting	
1.6.1 Machinery maintenance	
1.6.2. Access to operating positions and servicing points	
1.6.3. Isolation of energy sources	
Supplementary EHSR To Offset Hazards Due To The Mobility Of Machinery	
3.1.1 Definitions	
3.4.5 Means of access	
3.6.2 Markings	
Supplementary EHSR To Offset Hazards Due To Lifting Operations	
4.1.1. Definitions	

Figure 1: Applicable Essential Health and Safety Requirements (EHSRs) of the Machinery Directive (2006/42/EC) to Medical Devices.

in the MD as well as which should be applied for specific devices can be a difficult and time-consuming work [9]. Thus, efforts to develop guidelines for the manufacturers to clarify the requirements from MDD and MD that are applicable to exoskeletons can be helpful and time-saving.

2.4 Legal standards and robotic technologies

Through a more comprehensive and transparent regulatory framework, the EU regulations are aiming to enhance the safety and quality in the market while incentivizing innovation in the field.

The abovementioned regulations usually demand the manufacturer to demonstrate product safety. This is typically performed by applying (on itself voluntary) international standards. These standards provide secured methods for implementing certain features in technology, such as procedures on how to implement, analyze, and demonstrate the safety of new devices before they enter the market [6]. There are a number of standards that are formed and adapted for particular purposes. These include international standards made by the ISO and International Electro-technical Commission (IEC), which have an important role as they are made of international networks of national standard bodies. Standards are optional, but they can be mentioned to or integrated in regulations. The Conformity Assessment to the relevant regulations should use accredited service providers and uphold global principles [21].

However, at this time, only a few specified standards are available, and no specific testing methods are available for wearable robots [6]. For instance, product safety for medical devices that are classed in Medical Electrical Systems is technically defined in the IEC 60601-1 [28], which is a large family of standards for specific categories of medical devices. Wearable robots that are to be commercialized would normally choose to be compliant with this standard to guarantee their safety. The publication of ISO 13482 [29] concerning “Robots and robotic devices – Safety requirements for personal care robots” is one of the first specific output toward this direction that is relevant to wearable robots, since it covers exoskeleton-like robotics under the type “restraint-type physical assistant robots” [6]. The application of ISO 13482 is generally recommendable and highly encouraged for marketing of a personal care robot, since it provides a substantiation of conformity with European Directives. Developing a wearable robot in compliance with this new

standard, a designer can easily obtain a CE marking [23]. However, ISO 13482:2014 does not apply to robots as medical devices and currently the majority of exoskeletons have been developed for medical applications.

Those directives and standards do not cover many of the explicit and complex issues related to emerging robotic technologies, namely, human-robot interactions and the autonomous decision-making. The European Parliament lately opened a discussion for an EU-wide legislative action, focusing on civil law rules on robots [3]. This discussion aims to present law-making suggestions to secure a standard level of safety as well as to fully exploit the economic potential of robotics. The European Commission is organized to tackle matters of safety, liability, privacy, and the influence of robotics in workplace, health, industry, and environment [3].

3 Exoskeletons

Until now, most of the exoskeleton research has concentrated on medical applications of exoskeletons, such as rehabilitation and supporting mobility to physically disabled or injured persons (caused by various reasons, such as spinal cord injury, neurological disorders, stroke, etc.) [30]. Medical exoskeletons are used in rehabilitation and health-care centers supervised by medical experts [31]. However, exoskeletons can also be used to support regular tasks of daily life (i.e., walking, lifting heavy items, using stairs, and general movement) if the physical capacities of a person have been reduced as well as for the augmentation of physical abilities [21]. Exoskeletons developed for rehabilitation contexts can also be used in other contexts and *vice versa* [31]. Indeed, exoskeletons can be used for the rehabilitation of patients (i.e., medical) and also for assisting healthy users to transfer heavy objects, i.e., nonmedical. However, there are cases in between that are not very clear, like an assistive device for supporting the mobility of elderly [32].

It is essential to be aware of what is emerging in a regulatory sense, so that the accurate risk assessment and the applicable safety standards (either for a medical device or for a machine) can be carried out [21]. Some exoskeletons will be categorized and thus regulated as medical devices instead of machines, and this poses a borderline question (i.e., in which category they should be categorized: medical or nonmedical) since it may require to comply with different regulations. The ISO/IECs for medical and nonmedical exoskeletons are not the

same and must be followed, respectively, for successful marketing [32]. For medical exoskeletons aimed for rehabilitation, such regulations are currently under development by IEC SC62D and ISO TC299 JWG36; while for nonmedical exoskeletons, such as physical-assistant robots, ISO TC299 WG2 has been published [6,22]. As mentioned, ISO 13482 excludes medical applications, which means that it excludes medical robots that can perform tasks such as diagnosis, prevention, monitoring or treatment of diseases. [22]. Consequently, this could mean that getting ISO 13482 certification might not be beneficial if the robots are going to be compliant with the MDD [32].

The matter is how this borderline between medical and nonmedical wearable robots can be clearly defined. In cases where robots offer services that may be considered medical as well as nonmedical, then (regardless of the manufacturer's declaration for the intended use of the product) the device in both cases should be compliant with the MDD as described in the latest version of the regulation. This might be the case of exoskeletons: although they can have applications in rehabilitation and daily living tasks, and in both cases they will have to comply with the MDD [22].

3.1 Classification of exoskeletons

Exoskeletons – to be legally placed in the market – are required to obtain the CE certificate. Globally, there are several regulatory bodies with different purposes, procedures, and applications [33]. This creates a lot of perplexity in manufacturers' mind [34]. In the USA, powered exoskeletons (i.e., a category of device intended to assist paralyzed users recover the function of walking) have been formally classified as a Class II device with special controls by the FDA [35]. In the EU, there is no central government organization to publish certificates.

Various enterprises developing lower limb exoskeletons state that their device has already been approved as medical devices under the existing regulations. Such cases are the “HAL for Labor/Care Support” from Cyberdyne, which received ISO 13482:2014 as a wearable robot, the “Medical Robot Suit HAL,” which received a CE marking under the MDD, the ReWalk from ArgoMedical categorized as the Class II (USA) medical device, the Rex Bionics as Class I (EU, USA, and Australia) for rehabilitation use, and the EksoLegs from Ekso Bionics as Class I (USA and Australia) and Class IIa (EU) for rehabilitation use in hospitals. Nevertheless, the

provided information is brief and deficient, making it difficult to get a clear view of the precise compliance procedure required for exoskeletons under the existing international regulations. There is necessity for harmonization, standardization, and rationalization of licensing procedure around the world [37].

4 Formalization for ExosCE Rules

Legal and safety aspects create a huge motivation for explainable AI systems (i.e., systems in which the results of decision-making can be understood by human experts), since the EU cannot afford to deploy AI systems that make unexpected decisions, especially in the medical domain [11]. Legal AI models are often rule based [10,13,36], such as the presented formalization for ExosCE Rules in PSOA RuleML. In these models, a legal text is represented by rules that can express legal definitions, exceptions, arguments, and deductions. They can provide explanations as audit trails of how a particular conclusion was reached. In the ExosCE Rules model, any legal decision process that is complemented by the machine can be understood, explained, and re-enacted by humans. Furthermore, the syntax of the language is easily read and interpreted, facilitating the interdisciplinary understanding from nontechnical experts. PSOA RuleML has also been used for legal rules formalization in other use cases, such as Port Clearance Rules [36], Air Traffic Control Regulations [37,38], and MDD [16–18], providing evidence that PSOA RuleML is well suited to express real-world legal texts.

In this work, an example case study on commercializing wearable exoskeletons for rehabilitation is presented to highlight the basic modeling in medical exoskeletons. The aim of this recommendation is to provide a computational guidance: with the classification of exoskeletons based on the MDD; the Conformity Assessment including both the Essential Requirements of MDD and the EHSRs of the MD; and the marketability procedure in order to obtain the CE marking. Some explanatory parts of the code are used for the route through the compliance procedure (more can be found in Appendix A).

In the first part of formalization, the 22 rules are expressed with a three-level deep description of medical device characteristics described for abbreviation with (informal) three-symbol categories [17,18]. The relational conclusion argument $?m$ becomes the OID (Object Identifier) of the class :MedicalDevice of a frame with

:kind, :use, and :specificCase slots. An effective way to modify the translation of the legal text into rules is to add exceptions (specific cases) to the more generic rule to make the two cases of the rules disjoint.

One clause is used for each category of the rules, formed as the example below which formalizes the sentence “All active therapeutic devices intended to administer or exchange energy are classified as class IIa” [8].

```
% Rules for Active Devices - Rule 9
% Active therapeutic devices intended to exchange
or administer energy.
Forall ?m (
  :CategoryOfMedicalDevice(?m:A9a) :-
    ?m#:MedicalDevice(:kind->:Active
                      :use->:Therapeutic
                      :specificCase->:Energy))
```

The condition's predicate :MedicalDevice is a frame atom, where the hash infix # denotes *class membership* by typing an OID with its predicate, whereas the arrow infix, “->”, pairs each predicate-independent slot name with its filler.

In the second part of formalization, the aforementioned categories are connected with the class they reside in, forming an “Or” branch (disjunction). The predicate :CategoryOfMedicalDevices is a relationship that links the exoskeleton with the category of medical device that pertains. The generated categories are indicated by three letters which denote the three levels of categorization, e.g., :A9a, where A denotes an Active device; 9 denotes Rule 9; and a denotes the specific case “a,” i.e., :Energy. For the explanation of this formalization, the remainder of the article will be described based on category A9a (where exoskeletons belong, e.g., Eksolegs), while “[...]” denotes that some code fragments have been omitted to conserve space. Some of the categories in Class IIa, where :A9a belongs, are expressed in the following example:

```
% Classification Grouping: Class IIa
Forall ?m (
  :IsClassifiedIn(?m :IIa) :-
    Or(:CategoryOfMedicalDevice(?m :A9a)
      :CategoryOfMedicalDevice(?m :A10)
      :CategoryOfMedicalDevice(?m :A11) [...])
```

In the third part of formalization, the process required for a medical exoskeleton to be marketable is described. The different class-based routes for the Conformity Assessment of exoskeletons are depicted in Figure 2.

Figure 2: Class-based requirements for exoskeleton marketability.

The following rules are relational, on the Data log level of expressiveness:⁶

```
% Requirements for all Classes
Forall ?m (
  :MarketableMedicalDevice(?m) :-
    :HasCEwithNBN(?m))

Forall ?m (
  :HasCEwithNBN(?m) :-
    :DeclarationOfConformity(?m))
```

In Class IIa, as described in the example below, all the conditions of the “And” relation must be fulfilled to obtain the :DeclarationOfConformity.

⁶ That is, predicates that only have a variable, ?m.

```

Forall ?m (:DeclarationOfConformity(?m) :-
And(:IsClassifiedIn(?m:IIa)
:AppointingAnEAR(?m)
:ConformityAssessment(:device->?m:technicalFile->
:True
                                :vigilanceSystem->:Required
                                :harmonizedStandards->
                                :NonRequired)
:QualityAssurance(?m)
:ManufacturingRequirements(?m))

```

In the fourth part of formalization, all 64 Essential Requirements of the MDD (as described in Annex I of Chapter II) are encoded. The following example presents part of the code presenting the main headings of the Essential Requirements:

```

Forall ?m (:MDDManufacturingRequirements(? m) :-
And(:ChemicalPhysicalBiologicalProperties(?m) %
p.10 %
:InfectionMicrobialContamination (? m)% p.11 %
:SubstancesMedicalProductOrAbsorbed(? m)% p.12 %
[...]
:RisksByDevicesSupplyingEnergyOrSubstances(? m)%
p.21 %
:DevicesForUseByLayPersons(? m)))% p.22 %

```

In this part of the guideline, 12 EHRs of the MD that are applicable to Medical Devices are also added:

```

Forall ?m (MDManufacturingRequirements(?m) :-
And(:DefineGeneralTermsOfMD(?m :Checked)% p.1.1.1 %
:Lighting(?m :Checked)% p.1.1.4 %
:SeatingASIntegralPart(?m :Checked)% p.1.1.8 %
:ControlDevices(?m :Checked)% p.1.2.2 %
[...] ))

```

In the last part of formalization, data for specific exoskeletons were added directly in the KB. An example of an exoskeleton fact, i.e., EksoLegs, is encoded as follows:

```

:EksoLegs#:MedicalDevice(:kind->:Active
                        :use->:Therapeutic
                        :specificCase->:Energy)
:AppointingAnEAR(:EksoLegs)
:ConformityAssessment(:device->:EksoLegs
                        :technicalFile->:Yes
                        :vigilanceSystem->:Yes
                        :harmonizedStandards->:No)
[...]

```

5 A user-friendly interface for the essential requirement checklist

ExosCE Rules is implemented in the PSOA RuleML programming language and in the open-source engine PSOATransRun, currently in version 1.4.2. MS Excel worksheet can be utilized to create the user's checklist of the Essential Requirements for Conformity Assessment of the exoskeleton. The most important benefit is the usability of MS Excel due to the fact that many users find it more usable than programming languages for computational tasks. Thus, one of the objectives of Excel was to bring the advantages of additional programming language features to a system that is often not recognized as a programming language.

The user interface depends on Excel spreadsheet with pull-down menus to provide possible options for the requirements. Additionally, there are input messages, which are shown when the cell is selected, to provide brief instructions for each requirement as described in the directives (see Figure 3).

A script in Python translates user inputs of the Essential Requirements for the Conformity Assessment from the cells of the Excel to the PSOA RuleML code.

ExosCE KB executes reasoning and generates answers based on users' queries in PSOATransRun. In a future work, an online version of ExosCE can also be deployed to enable exoskeleton developers to add exoskeleton facts and check compliance requirements.

6 Query answering by PSOATransRun

In this section, representative copy&paste-ready queries are posed to the KB and demonstrate the answers obtained by PSOATransRun.

To obtain the category of an exoskeleton, the following deductive query is employed, binding the answer to the output variable ?g.

```

> :CategoryOfMedicalDevice(:EksoLegs ?g)
?g=<http://psoa.ruleml.org/usecases/
MedicalDevices#A9a>

```

Using the top-level predicate :IsClassifiedIn it can be queried whether an exoskeleton, e.g., :IsClassifiedIn(:EksoLegs :IIa), belongs to a specific class, i.e., IIa (Answer: Yes).

Figure 3: A checklist of the Medical Devices Directive (MDD) and Machinery Directive (MD) safety requirements in MS Excel.

Abstracting this query (e.g., the constant `:IIa` becomes the variable `?c`), it could also be posed as a generalized query `:IsClassifiedIn(?m ?c)` to deduce all exoskeletons and their corresponding classes, using two output variables (`?m` and `?c`).

More queries can be asked on the marketability and conformity requirements of exoskeletons. In the example of `:EksoLegs` represented by code `:MDN0310b`, `PSOATrans-Run` returns a “Yes”-answer in the following queries:

```
:IsClassifiedIn(:EksoLegs :IIa)
:RegisterWithTheECA(:EksoLegs)
:AppointingAnEAR(:EksoLegs)
:DeclarationOfConformity(:EksoLegs)
:HasCEwithNBN(:EksoLegs)
:MarketableMedicalDevice(:EksoLegs)
```

% Answer for all: Yes %

All the marketable exoskeletons can also be asked, using, e.g., the input variable `?m`, by posing the query

```

C:\Windows\System32\cmd.exe - java -jar PSOATransRunLocal.jar -x "C:\...
Microsoft Windows [Version 10.0.18362.356]
(c) 2019 Microsoft Corporation. All rights reserved.

C:\Users\Sophie\Desktop\PSOA RuleML>java -jar PSOATransRunLocal.jar
-x "C:\Program Files (x86)\XSB" -i ExoskeletonsRules.psoa -a
PSOATransRun1.3.2[PSOA2Prolog,XSBProlog]
KB Loaded. Enter Queries:

> :MarketableMedicalDevice(?m)
Answer(s):
?m=<http://psoa.ruleml.org/usecases/MedicalDevices#RexBionics>
?m=<http://psoa.ruleml.org/usecases/MedicalDevices#EksoLegs>

> :IsClassifiedIn(?m ?c)
Answer(s):
?m=<http://psoa.ruleml.org/usecases/MedicalDevices#RexBionics> ?c=<h
http://psoa.ruleml.org/usecases/MedicalDevices#I>
?m=<http://psoa.ruleml.org/usecases/MedicalDevices#EksoLegs> ?c=<htt
p://psoa.ruleml.org/usecases/MedicalDevices#IIa>

>

```

Figure 4: Queries in Positional-Slotted Object-Applicative TransRun (PSOATransRun).

:MarketableMedicalDevice(?m). Moreover, all exoskeletons that satisfy one or more specific marketability requirements can be obtained as shown below (where part of the namespace is omitted to conserve space) and in Figure 4:

```

> :MarketableMedicalDevice(?m)
Answer(s):
?m=<.../MedicalDevices#RexBionics>
?m=<.../MedicalDevices#EksoLegs>

```

The complete KB coupled with the database source, the excel sheet for the requirements' checklist, the Python script for converting the database into a PSOA RuleML code, and a Readme File can be found at <http://users.ntua.gr/salmpiani/ExosCE/>.

7 Discussion and conclusions

For wearable robots companies, there is a continuous necessity to balance compliance, quality, and agility;

thus, there is a need for automation of procedures to streamline the necessary time to obtain premarket approval and allocate exoskeleton products to the market. This article covers the rapidly evolving area of exoskeletons and their related regulations, so that the current legal framework and the future challenges can be realized and addressed.

The present work has demonstrated a formalization of medical device and machinery regulations that are relevant to exoskeletons as part of a logical KB, leading to a computational decision model in PSOA RuleML. This executable formalization was tested by implementing queries on the PSOATransRun engine and evaluating the answers retrieved. The resulting KB is capable of answering queries regarding the classification and marketability of exoskeletons aiming at compliance with the Regulation MDD (EU) 2017/745 and MD (EU) 2006/42.

In addition to representing the essential requirements of 2017/745 and the related EHRS of 2006/42 precisely enough within the scope of the CE-registration procedure, this development aimed to a formalization

that could be verifiable by lawyers, medical experts, and programmers alike. For this reason, we also provided a tool to translate the safety requirements from the MS Excel format to a PSOA RuleML code, so that the non-technical users can read and understand the PSOA RuleML language and the presentation syntax.

The rules developed in this work are independent, autonomous pieces of knowledge, enabling future amendments/amelioration of the present regulation (e.g., enrichment with postmarketability and clinical evaluation requirements), as well as other exoskeleton-relevant regulation or supporting standards (e.g., General Data Protection Regulation, ISO 13485 for Medical devices, ISO TC299 for Robots and Robotic Devices, etc.) or extension of the current work, acting as a groundwork for other countries' regulations (e.g., USA, India, Japan, etc.). This can contribute to the effort of unifying legal frameworks evolved to a computational format, as part of legal informatic efforts.

In the future, we plan to introduce a user-friendly online tool for the requirement checklist, which will use the PSOATransRun reasoner and the ExosCE KB as a back end. Moreover, we can incorporate possible future ontologies (using PSOATransRun's built-in N3 to a PSOA translator [39]) or databases for Exoskeletons, enriching our KB. This KB could be extended to support additional requirements, e.g., from ISOs, so that an exoskeleton can be checked against all requirements. Part of our future interest is to disseminate this tool to stakeholders (robotic companies, lawyers, researchers, medical experts, etc.) through European robotic-related networks (such as Cost Actions, Horizons, Erasmus, etc.) as well as to utilize it in multidisciplinary courses for technical and nontechnical students in medical, engineering, and legal fields.

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Appendix

ExosCE rules KB in PSOA RuleML

A representative fragment of the PSOA RuleML code is given below. The whole ExosCE KB with the MS Excel and the Python script can be found at <http://users.ntua.gr/salmpiani/ExosCE/>. Further instructions can be found at <http://users.ntua.gr/salmpiani/ExosCE/README.txt>. For more detailed directions, an email can also be sent to the authors.

```
% Rules for Active Devices
```

```
% Rule 9
```

```
% Active therapeutic devices intended to exchange  
or administer energy.
```

```
Forall ?m (
```

```
  :CategoryOfMedicalDevice(?m :A9a) :-  
  ?m#:MedicalDevice(:kind->:Active  
    :use->:Therapeutic  
    :specificCase->:Energy))
```

```
% Classification Grouping: Class IIa
```

```
Forall ?m (
```

```
:IsClassifiedIn(?m :IIa) :-  
  Or(:CategoryOfMedicalDevice(?m :N2a)  
    :CategoryOfMedicalDevice(?m :N2b)  
    :CategoryOfMedicalDevice(?m :N3b)  
    :CategoryOfMedicalDevice(?m :N4c)  
    :CategoryOfMedicalDevice(?m :I5b)  
    :CategoryOfMedicalDevice(?m :I6)  
    :CategoryOfMedicalDevice(?m :I7)  
    :CategoryOfMedicalDevice(?m :I8a)  
    :CategoryOfMedicalDevice(?m :A9a)  
    :CategoryOfMedicalDevice(?m :A10)  
    :CategoryOfMedicalDevice(?m :A11)  
    :CategoryOfMedicalDevice(?m :A12)  
    :CategoryOfMedicalDevice(?m :S16b)  
    :CategoryOfMedicalDevice(?m :S17)  
    :CategoryOfMedicalDevice(?m :S19a)  
    :CategoryOfMedicalDevice(?m :S20)  
    :CategoryOfMedicalDevice(?m :S21b)))
```

```
% Main paragraphs of Essential Requirements of MD.
```

```
Forall ?m (:MDDManufacturingRequirements(?m) :-
```

```
  And(  
    :ChemicalPhysicalBiologicalProperties(?m) % p.10 %
```

```
:InfectionMicrobialContamination(?m) % p.11 %  
:SubstancesMedicalProductOrAbsorbed(?m) % p.12 %  
:IncorporatingMaterialsOfBiologicalOrigin(?m) %  
  p.13 %  
:InteractionWithTheirEnvironment(?m) % p.14 %  
:DiagnosticOrMeasuringFunction(?m) % p.15 %  
:ProtectionAgainstRadiation(?m) % p.16 %  
:ElectronicProgrammableSystems (?m) % p.17 %  
:ActiveDevices(?m) % p.18 %  
:ActiveImplantableDevices(?m) % p.19 %  
:ProtectionAgainstMechanicalAndThermalRisks(?m) %  
  p.20 %  
:RisksByDevicesSupplyingEnergyOrSubstances(?m) %  
  p.21 %  
:DevicesForUseByLayPersons(?m) % p.22 %  
))
```

```
% EHRS of the Machinery Directive (2006/42/EC)  
that are applicable to Medical Devices.
```

```
Forall ?m (MDManufacturingRequirements(?m) :-  
  And(  
    :
```

```
      DefineGeneralTermsOfMD(?m :Checked) % p.1.1.1 %  
      Lighting(?m :Checked) % p.1.1.4 %  
      SeatingASIntegralPart(?m :Checked) % p.1.1.8 %  
      ControlDevices(?m :Checked) % p.1.2.2 %  
      ErrorsOfFitting(?m :Checked) % p.1.5.4 %  
      MachineryMaintenance(?m :Checked) % p.1.6.1 %  
      AccessToOperatingPositionsAndServicingPoints(?m  
        :Checked) % p.1.6.2 %  
      IsolationOfEnergySources(?m :Checked) % p.1.6.3 %  
      DefineMobilityTermsOfMD(?m :Checked) % p.3.1.1 %  
      MeansOfAccess(?m :Checked) % p.3.4.5 %  
      MarkingsForDeivicesIn311(?m :Checked) % p.3.6.2 %  
      DefineTermsOfMDForLiftingOperations(?m :Checked)  
    % p.4.1.1 %  
  ))
```

```
% Marketability Requirements for all Classes
```

```
Forall ?m (
```

```
  :MarketableMedicalDevice(?m) :-  
  :HasCEwithNBN(?m))
```

```
Forall ?m (
```

```
  :HasCEwithNBN(?m) :-
```

```

:DeclarationOfConformity(?m))                                :manufacture-
% Requirements for Class IIa                                   >:Required))

Forall ?m (:DeclarationOfConformity(?m) :-                    % Exoskeleton Fact: EksoLegs
  And(:IsClassifiedIn(?m :IIa)
    :AppointingAnEAR(?m)
    :ConformityAssessment(:device->?m
      :technicalFile->:True
      :vigilanceSystem->:Required
      :harmonizedStandards-
        >:NonRequired)
    :QualityAssurance(?m))'
    :ManufacturingRequirements(?m))

Forall ?m (:ManufacturingRequirements(?m) :-
  And (:MDDManufacturingRequirements(?m)
    :MDManufacturingRequirements(?m)))

% Requirements for Production Quality -
% Annex V, EN ISO 13485:2003

Forall ?m (:QualityType(?m :ProductionQuality) :-
  :RequirementsOfQualityType(:device->?m
    :design->:NonRequired
    :EksoLegs#:MedicalDevice(:kind->:Active
      :use->:Therapeutic
      :specificCase->:Energy)
    :AppointingAnEAR(:EksoLegs)
    :ConformityAssessment(:device->:EksoLegs
      :technicalFile->:Yes
      :vigilanceSystem->:Yes
      :harmonizedStandards->:No)
    :RequirementsOfQualityType(:device->:EksoLegs
      :design->:No
      :manufacture->:No)
    :Design(:EksoLegs :Checked) % p.10.1 %
    :ContaminantsResidues(:EksoLegs :Checked) % p.10.2 %
    :MedicinalProducts(:EksoLegs :Checked) % p.10.3 %
    :IngressOfSubstances(:EksoLegs :Checked) % p.10.5 %
    :SizePropertiesOfParticles (:EksoLegs :Checked) %
      p.10.6 %
    [...])
  )

```