ExosCE: A Legal Framework System for Exoskeleton Compliance

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Outline

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Introduction

- Wearable robots are devices intended to improve the quality of users' life.
- Exoskeletons are one of the most widespread wearable robots.
- Mostly used in medical applications: Medical Devices Directives.
- Manufacturers must also specify if their exoskeletons can be categorized as machines: Machinery Directives.

Introduction

This rule-based system is an initial attempt:

- to develop a computational rule format of the classification rules and the conformity assessment procedures,
- to supplement it with Facts about exoskeletons,
- to test, with queries the accuracy of the developed computational model.

A computational guideline to assist stakeholders of exoskeletons.

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An Overview of the Regulatory Framework of Wearable Robots

- The world of wearable robots is heterogeneous with wide diversification in potential risks.
- The European Union Law does not contain explicit rules on robots.
- Machinery Directive 2006/42/EC (MD) and Medical Devices Directive 2017/745/EC (MDD).

Machinery Directive (EU) 2006/42

- Refers to machines mainly defined as devices with power circuits, actuators, control, and at least one moving part.
- Basic Essential Health and Safety Requirements (EHSR) for devices to be placed on the market.
- Most robots so far have been categorized as machines.
- Harmonised standards published under the MD do not involve the combination of machine and wearable device - need improvement/ updating.

Medical Device Directive (EU) 2017/745

- The Medical Devices Directive refers to any device designed to meet a medical need and used for diagnostic and/or therapeutic purposes.
- The updated version will be in force in 2020.
- The classification criteria for four classes (Class I, IIa, IIb, III) are described with 22 rules.
- 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.

Comparison of MDD and MD Safety Requirements

- According to the latest version of the MD, manufacturers must specify if their products can also be categorized as machines - comply with the MD as well.
- Basic feature of a machine is the accessibility of the moveable parts - WR and exoskeletons fall into the category of machines.
- Annex I: around fifty EHSRs - they are not all applicable to medical devices. Twelve requirements can be considered applicable.

Legal Standards and Robotic Technologies

- International standards made by ISO and IEC.
- Standards are optional, but can be mentioned to or integrated in regulations.
- A few specified standards available for Wearable Robots.
- Product safety for MD that are classed in Medical Electrical Systems: IEC 60601-1
- Robots and robotic devices - Safety requirements for personal care robots: ISO 13482

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Exoskeletons

- Medical exoskeletons can be used to other contexts and vice versa.
- ISO/IECs for medical and non-medical exoskeletons are not the same.
- Medical exoskeletons:IEC SC62D and ISO TC299 JWG36
- Non-medical exoskeletons: ISO TC299 WG2, ISO 13482
- Where robots offers services that may be considered medical as well as non-medical, then the device should be compliant to MDD (e.g., exoskeletons).
- The guidance to stakeholders is to apply for both ISOs.

Classification of Exoskeletons

Examples of exoskeletons that have been approved as medical:

1. “HAL for Labor/Care Support” from Cyberdyne, ISO 13482:2014 as WR
2. “Medical Robot Suit HAL”, CE mark under the MDD
3. ReWalk from ArgoMedical, class II (USA) medical device
4. Rex Bionics, Class I (EU, USA and Australia) for rehabilitation use
5. EksoLegs from Ekso Bionics, Class I (USA and Australia) and Class IIa (EU) for rehabilitation use in hospitals

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ExosCE Rules Formalization in PSOA RuleML

Positional-Slotted Object-Applicative (PSOA) RuleML:

- It supports object-relational data facts as well as transformation rules over them.
- Legal-AI models are often rule-based.
- In ExosCE Rules model, any legal decision process that is complemented by the machine can be understood, explained and re-enacted by humans.

ExosCE Rules Formalization

Our formalization “ExosCE Rules” consists of five parts:

1. The 22 classification rules of the MDD regulation.
2. The categories that belongs in each class.
3. The Essential Requirements of the MDD and the Essential Health and Safety Requirements of the MD.
4. The marketability procedure according to the conformity assessment options.
5. Representative data (facts) of exoskeletons.

ExosCE Rules Formalization

- The **risk-based classification rules** are linked to (informal) categories.
- One clause is used for each category, e.g. in Rule 9.

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

- `:MedicalDevice` is a *frame atom*.
- The predicate `:CategoryOfMedicalDevices` is a *relationship*.

Categories and Classes

The categories are connected with the class forming an ‘Or’ branch (disjuction).

```
% Classification Grouping: Class IIa
 Forall ?m (
:IsClassifiedIn(?m :IIa) :-
       Or(:CategoryOfMedicalDevice(?m :N2a)
          :CategoryOfMedicalDevice(?m :N2b)
          :CategoryOfMedicalDevice(?m :I6)
          :CategoryOfMedicalDevice(?m :I7)
          :CategoryOfMedicalDevice(?m :I8a)
          :CategoryOfMedicalDevice(?m :A9a)
          :CategoryOfMedicalDevice(?m :A10)
          :CategoryOfMedicalDevice(?m :S21b)) [...]  )
```

Essential Requirements of MDD

- All 64 the Essential Requirements of MDD (EU) 2017/745, Annex I Chapter II.

```
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 % [...] ))
```

Exoskeletons Rules Formalization

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

Applicable to exoskeletons EHSR of MD

- Twelve EHRS of the Machinery Directive that 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 %
    [...] ))
```

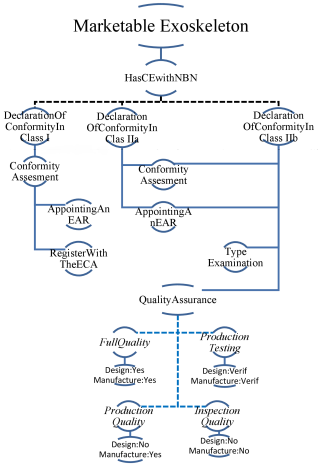
Marketability of Medical Devices

- **Conformity assessment** routes of each class and the implying **marketability**.

```
% Requirements for Class IIa
Forall ?m (:DeclarationOfConformity(?m) :-
 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) ))
```

Marketability of Exoskeletons



Representative Data (Facts) of Medical Devices

Data for exoskeletons (Facts) were added in the KB.

```
: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 % [...]
```

A user-friendly interface for the Requirements Checklist

We utilize the MS Excel worksheet to create the user's checklist of the Requirements for the conformity assessment of the exoskeleton.

A Python script can translate user inputs of the Requirements from Excel to PSOA RuleML code.

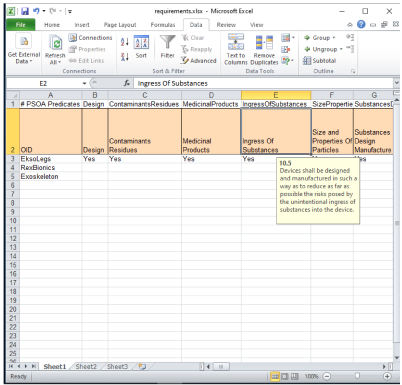


Figure: Excel to add exoskeletons facts.

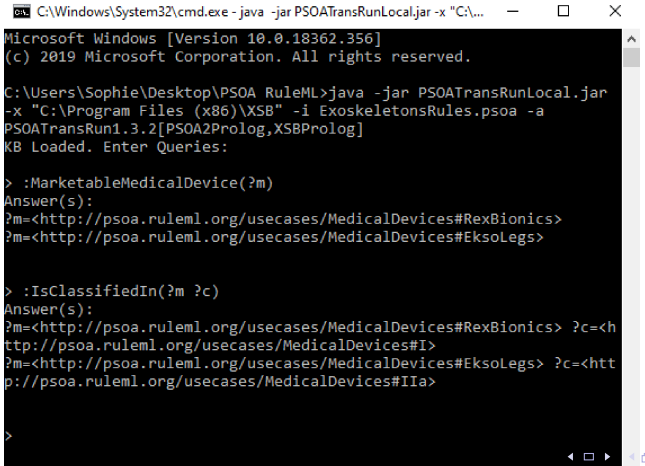
Outline

PSOATransRun

- The Prolog instantiation of PSOATransRun, currently in version 1.4.2, 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)).
```

A user-friendly interface for the Requirements Checklist



Representative Queries

```
:ConformityAssessment(:device->:EksoLegs :technicalFile->:NonRequired
    :vigilanceSystem->:Required :harmonizedStandards->:NonRequired)
:DeclarationOfConformity(:EksoLegs)
:HasCEwithNBN(:EksoLegs)
:ManufacturingRequirements(:EksoLegs)
% Answer for all: Yes %

:IsClassifiedIn(:EksoLegs ?c)
?g=<http://psoa.ruleml.org/usecases/MedicalDevices#IIa>

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

Outline

Conclusions

- We have demonstrated a formalization of exoskeletons regulations 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 exoskeletons.
- This has created an initial opportunity for decision support using this rule formalization in the compliance with the Regulations (EU) 2017/745 and 2006/42.

Download the code:

http://users.ntua.gr/salmpani/ExosCE/

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