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SusFE

D1.5 SusFE standardization, and policies document detailing implemented standards and policies, risk analysis and guidance based on SusFE learnings

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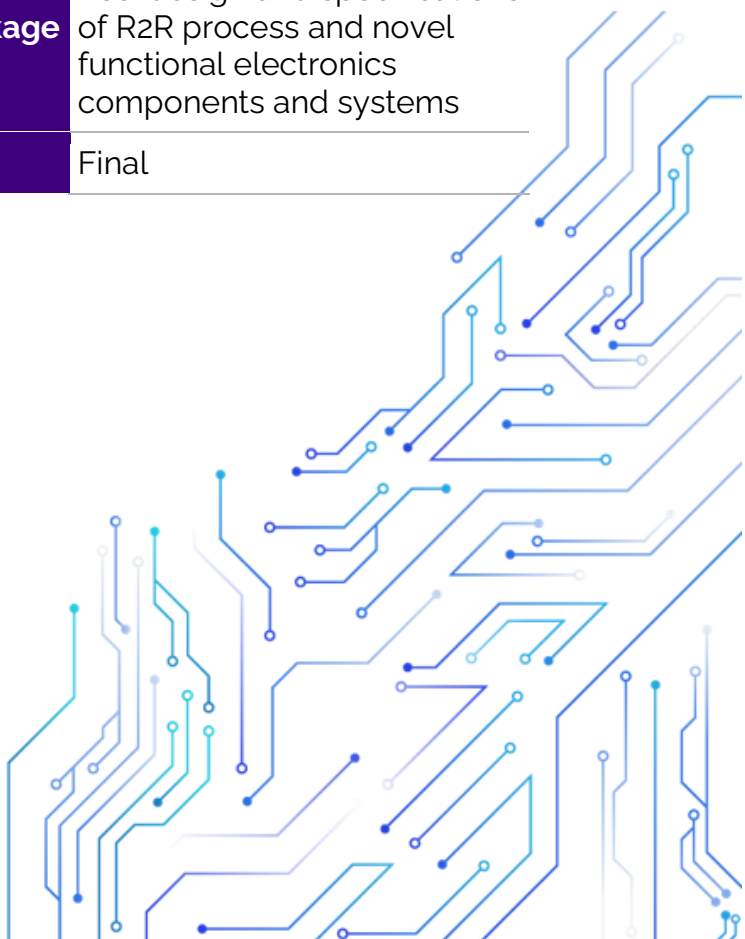

Authors

Name and surname	Partner name	e-mail
BLOCH Alexandre3	BeFC	alexandre.bloch@befc.fr
PANIS Caroline	BeFC	caroline.panis@befc.fr

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Abstract

This report provides an overview of the standardization, policies, certification, norms, and regulations surrounding medical devices. Medical devices are critical components of modern healthcare, and their safety and effectiveness are paramount. To ensure that medical devices meet rigorous safety and quality standards, regulatory agencies and standardization bodies have developed a complex web of rules and regulations.
Overall, this report provides an in-depth look at the complex landscape of medical device standardization, policies, certification, norms, and regulations, highlighting the importance of ensuring the safety and effectiveness of medical devices for the benefit of patients in EU.

Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

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About this deliverable

Deliverable context

Table 1. Deliverable context

PROJECT ITEM IN THE DOA	RELATIONSHIP
Project Objectives	Overview of the standardization, policies, certification, norms, and regulations surrounding medical devices.
Exploitable results	List of standardizations
Workplan	D1.5.1 is attributed to WP1 Eco-design and specifications of R2R processes and novel functional electronics components and systems. The tasks involved in the preparation of this deliverable are: T1.4 Standardization and policies
Milestones	D1.5.1 is a key deliverable for the acceptance and utilisation of the developed solutions, ensuring the SusFE developments and solutions comply with relevant standards
Deliverables	Standardization Report
Risks	Non-identification of a critical standard

1 Definition

The purpose of this part is to recall and define all the important and necessary key words for the good understanding of all the work carried out in the SusFE project

1.1 Sustainable Development

Development that meets the needs of the present without compromising the ability of future generations to meet their own needs

1.2 Recycle

To sort and collect rubbish in order to treat it and produce useful materials that can be used again

1.3 Disposable

(Of an article) intended to be thrown away after use

1.4 Biodegradation

The breakdown of organic matter by microorganisms, such as bacteria and fungi

1.5 Biodegradable

(Of a substance or object) capable of being decomposed by bacteria or other living organisms and thereby avoiding pollution.

1.6 Compostable

(Of organic matter, especially kitchen waste) able to be made into compost.

1.7 Compost

Decayed organic material used as a fertilizer for growing plants.

1.8 Bio-based material

Material intentionally made from substances derived from living (or once-living) organisms

1.9 Eco-Friendly

Not harmful to the environment; or trying to help the environment

1.10 Biocompatible

Used to describe something that does not have a harmful effect on the human body

1.11 Organic

Relating to or derived from living matter

1.12 Bio-sourced

Is a material intentionally made from substances derived from living (or once-living) organisms.

2 Power Supply

This part focuses on the power supply of the device developed in the SusFE project: the bio-enzymatic fuel cell.

2.1 Bioenzymatic Fuel Cell

A bioenzymatic fuel cell is a sustainable paper biofuel cell, which is thin, light, flexible and can be disposable, compostable or recyclable. To generate energy, enzymes are used to convert glucose and oxygen into electricity.

Environmental objectives: The main objective is to develop a low environmental impact energy source that can be integrated into portable electronic devices as an alternative to miniature batteries, such as lithium batteries. This will reduce pollution related to lithium extraction and battery production as well as emissions related to the collection and recycling of existing batteries.

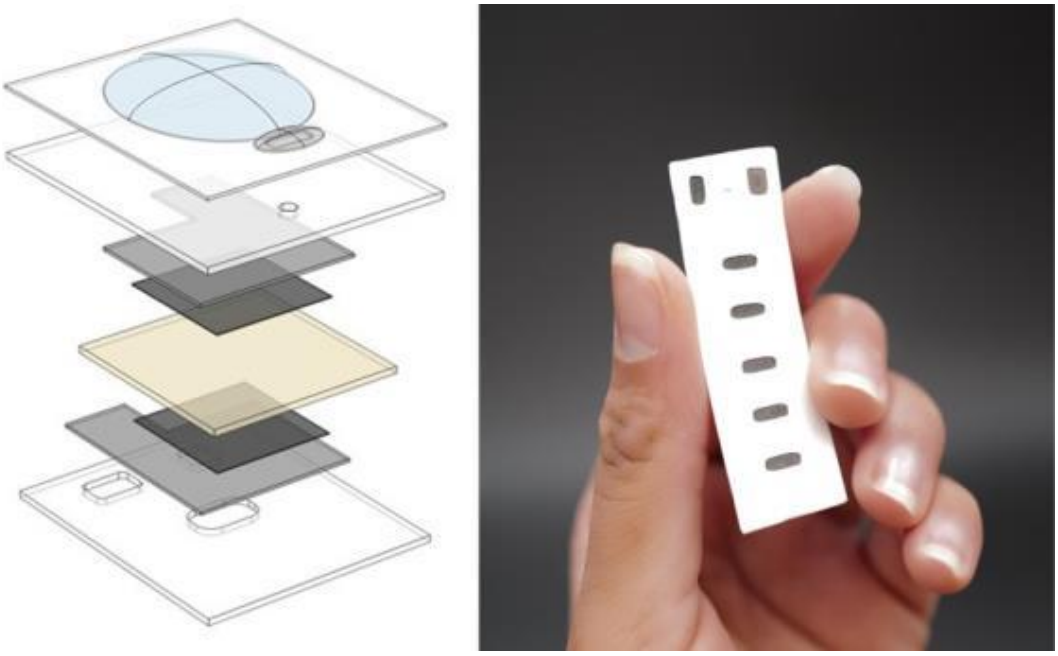

Figure 1: BeFC - Bioenzymatic fuel cell

2.1.1 Summary of cell characteristics

In this part, the focus will be on the characteristics related to the end of life of cells. The main objective for BeFC is not to disturb the end of life of the objects on which the cell is affixed.

2.1.1.1 Disposable

The power supply proposed by BeFC is **100% disposable**. This has been proven by an approved technical centre and means that during the recycling process, the cell can be disposed of in one of the main product recycling steps. Thus, the cell is **not necessarily recyclable** itself, but does **not interfere** with the recycling of the object in which it is located.

2.1.1.2 Recyclable

The power supply offered by BeFC is over 96% recyclable. This has been proven by an accredited technical centre and means that during the recycling process, the cell can be recycled to reuse the materials that compose it. Thus, in addition to not interfering with the recycling of the product in which the cell is located, it contributes to the creation of new recycled materials

2.1.1.3 Biodegradable and non-phytotoxic

The power supply offered by BeFC is more than 50% biodegradable in 56 days and non-phytotoxic, proven by an in-house study. Hence, one possible end of life for the products developed in the SusFE project could be biodegradation.

2.1.2 Nature of the power supply

To identify the standardizations and policy that apply to the energy source, it is necessary to characterize the nature of the source. One of the first approaches is to consider the bioenzymatic cell as a battery.

Problem raised: After a study of the texts characterizing a battery, it appears that there is a difference between the definition of a battery in these texts and the technology developed by BeFC.

Question raised: Are we considered as a battery? Is directive 2006/66/EC applicable?

Table 2: comparison between the 2006/66/EC directive vs. the BeFC technology

Directive 2006/66/EC (Article R543-125)	BeFC
Source of electrical energy generated by direct conversion of chemical energy	Biochemical
Portable battery or accumulator' means any battery, button cell, battery pack or accumulator that is sealed	Not sealed
'button cell' means any small round portable battery	Many shapes

To answer this question, a series of interviews with different entities was organized. The list of partners interviewed is exemplified below:

- CITEO: specialized in the recycling of household packaging and graphic paper

- Corepile: is a State-approved eco-organization that collects and recycles portable batteries and accumulators on behalf of its members who place them on the market in France

- Screlec: is a non-profit eco-organization approved by the State for the Extended Producer Responsibility (EPR) of portable batteries and accumulators. Its mission is to organize the collection and recycling of EEE waste in France

- Ecologic: is a state-approved eco-organization for the collection and processing of WEEE.

Following these interviews and after an internal study, it turns out that the bioenzymatic cell proposed by BeFC is considered as a "battery", Meaning that the directive 2006/66/CE is directly applicable. Indeed, the technology proposed by BeFC is a power supply. Moreover, BeFC cell is intended to replace current batteries, such as button cells for example.
Moreover, the fact that the bioenzymatic cell is not sealed does not influence its nature. There are other technologies that are not sealed but considered as a battery.

And finally, the cell can be compared to a flow battery because it uses oxygen from the air as fuel. So, all these points support the fact that the directive is applicable.

3 Electronics

3.1 CE marking

Figure 2: CE marking

The CE marking assures the compliance of a product with the European directives to guarantee its safety and conformity.

CE marking is compulsory to trade products in the European Economic Area (EEA). The EEA includes EU countries, Iceland, Liechtenstein, and Norway. Once the manufacturer has tested his products and assume they are compliant, he's allowed to affix himself the CE marking on them. However, the medical area requires further measures, and a notified body is required to affix the CE marking on medical devices.

The procedure to follow is the one below:

1. Identify the applicable directives
2. Verify the product specific requirement
3. Verify if a notified body is required
4. Test the products according to the standards
5. Gather the tests results and put together a technical dossier documenting conformity
6. Sign the EU declaration of conformity

The time needed to run all the tests and assure the conformity of the product highly depend on the number of directives and standards the product is subject to. It usually takes months to gather every data. To trade products in the medical area, the average time needed is on average 18 months.

SusFE product will likely be subject to the following directives:

- 2014/35/EU: low voltage directive (LVD): 3.1.1
- 2014/30/EU: electromagnetic compatibility (EMC): 3.1.2
- 2014/35/EU: radio equipment directive (RED): 3.1.3
- 2011/65/EU: restriction of Hazardous Substances (RoHS): 3.1.4
- 2012/19/EC: WEEE directive: 3.4
- 2017/745/EU: medical devices regulation (MDR): 4.1
- 2009/125/EC: ecodesign requirements for energy-using and energy-related products

CE marking applies to SusFE product.
The UKCA marking, very similar to the CE marking, will be compulsory to sell products in the UK from the 30th of June 2023.

3.1.1 Low voltage directive

The LVD directive ensures the safety of on equipment. It concerns small devices that fall under the voltage capacity of 50 to 1000 volts for alternating current and 75 to 1500 volts for direct current. SusFE product is not subject to LVD.
LVD tests don't apply to SusFE product.

3.1.2 Electromagnetic compatibility

The EMC directive ensures that the side effects of an electronic device do not disturb another electronic device in close proximity. It covers two different aspects. It enhances immunity of a device (its ability to function correctly in the presence of interferences), and it controls the electromagnetic disturbances of the device. Tests required:

- **radiated immunity**: to analyse how a device perform when it is exposed to external electromagnetic energy
- **radiated emissions**: to measure the electromagnetic disturbances the device generates
- **conducted immunity**: to measure the response of a device to electromagnetic energy generated by another source and accidentally conducted to the device under test
- **conducted emissions** : to measure the level of internal electromagnetic energy that may travel along a conductor and impact another system

Only radiated EMC tests apply to SusFE product.

3.1.3 Radio equipment directive

The RED directive ensures the electromagnetic efficient usage of radio spectrums. It concerns products using wireless connectivity such as RFID, NFC, Bluetooth, WIFI, Sigfox…
RED tests apply to SusFE product.

3.1.4 Restriction of Hazardous Substances

The RoHS directive ensures that the 10 identified hazardous substances in electrical and electronic equipment are kept under a certain level.

The 10 concerned substances are:
- Lead (Pb)
- Mercury (Hg)
- Cadmium (Cd)
- Hexavalent chromium (Cr6+)
- Polybrominated biphenyls (PBB)
- Polybrominated diphenyl ether (PBDE)
- Bis(2-Ethylhexyl) phthalate (DEHP)
- Butyl benzyl phthalate (BBP)
- Dibutyl phthalate (DBP)

- Diisobutyl phthalate (DIBP)

Test Item	EU Regulatory Limit	
	Quantity	Percentage
Cadmium (Cd)	100 ppm	0.01%
Lead (Pb)	1000 ppm	0.1%
Mercury (Hg)	1000 ppm	0.1%
Hexavalent Chromium (Cr^{6+})	1000 ppm	0.1%
PBBs	1000 ppm	0.1%
PBDEs	1000 ppm	0.1%
Di-(2-ethylhexyl) phthalate (DEHP)	1000 ppm	0.1%
Butyl Benzyl phthalate (BBP)	1000 ppm	0.1%
Dibutyl phthalate (DBP)	1000 ppm	0.1%
Di-isobutyl phthalate (DIBP)	1000 ppm	0.1%

Figure 3: RoHS restrictions

1ppm = 1mg/kg

Different tests can be run to identify the amount of those substances. The common ones are the XRF spectrometry method, and the chromatography.
RoHS compliance applies to SusFE product.

3.2 REACH

*REACH stands for **REACH** stands for **R**egistration, **E**valuation, **A**uthorisation and **R**estriction of **CH**emicals.*

REACH has been implemented to provide a high level of protection of human health, and of the environment, by securing the use of chemicals.
REACH compliance includes the registration, evaluation, authorizations, and restrictions of the chemical substances.
Registration: All chemical substances manufactured or imported into the EU in quantities exceeding 1 metric ton per year, not matter their hazardousness, need to be identified and registered with the ECHA (*European chemical agency*). The identification of a chemical requires the chemical name, number, and the chemical composition.
Evaluation: The registered chemicals need to be REACH compliant by checking the eight key endpoints: Compliance checking of substances of concern: genotoxicity, repeated dose toxicity, prenatal developmental toxicity, reproductive toxicity, carcinogenicity, long-term aquatic toxicity, biodegradation, and bioaccumulation
Authorisation: According to the results, the manufacture and importation of the chemical substances are authorized.
Restriction: Some restrictions can be identified and need to be respected and dealt with.

REACH gives a particular interest to substance of very high concern (SVHC). A substance is considered as SVHC when it is:

- Carcinogenic
- Mutagenic
- Toxic to reproduction
- Persistent, bioaccumalative and toxic
- Persistent and very bioaccumalative
- When there is scientific evidence of potential serious effects to human health or to the environment

The list of SVHC is available to the following link:
https://echa.europa.eu/fr/candidate-list-table

Reach compliance does not apply to SusFE product as soon any substance is imported or manufactured in quantities exceeding 1 metric ton per year.

3.3 GUILEDINES

Each time a new chemical substance is added to SusFE project, the following steps must be followed:

- Identify properly the chemical substance
- Check if the substance is in the SVHC list
- Quantify the quantity of the substance manufactured or imported per year
- Ensure that the substance is REACH compliant
- Ensure a proper storage and good usage practices of the substance, as well as the overall safety, all along SusFE project

Each time a new component is added to SusFE project, the following steps must be followed:

- Identify the component
- Make sure the component is RoHS compliant
- Define the impact of the component integration on the product behaviour
- Check if the RED and EMC tests need to be performed again *(if applicable at the project stage)*
- Manage the component storage as well as the overall safety, all along SusFE project

Each time a new protocol of communication is added to SusFE project, the following steps must be followed:

- Check if there is any regulation applicable to the added protocol of communication
- Make sure the product is compliant

- Check if the RED and EMC tests need to be performed again *(if applicable at the project stage)*

Each time a new substance or material, other than those listed above, is added to SusFE project, the following steps must be followed:

- Check if there is any regulation applicable the added part
- Manage the overall safety, all along SusFE project

3.4 WEEE directive

3.4.1 EEE definition

EEE stands for Electrical and Electronic Equipment

The article R543-172 of the Environmental Code defines an EEE as followed:

An "electrical and electronic equipment" designates all equipment functioning with an electric current or electromagnetic fields. It refers as well to all equipment that generate, transfer or measure these currents and fields, designed to be used at a voltage not exceeding 1 000 volts in alternating current and 1 500 volts in direct current.

EEE have been classified into 8 categories since August 15, 2018:

1. Heat exchange equipment
2. Displays, monitors and equipment including screens with a surface area greater than 100 cm^2.
3. Lamps
4. Large equipment
5. Small equipment
6. Small IT and telecommunications equipment
7. Photovoltaic panels
8. Pedal-assisted bicycles and motorized personal transport devices

SusFE product would be part of the 5^{th} category, small equipment.

3.4.2 WEEE definition

WEEE stands for Waste Electrical and Electronic Equipment.
WEEE regulation covers 3 aspects of the EEE end of life:

- The collection
- The recycling
- The recovery

WEEE management is part of the European Parliament, under the directive 2012/19/EU.

It aims to reduce the environmental impact of electronic waste, encourage the efficient use of resources, and promote sustainable development in the EU.

The targeted collection rate for WEEE in Europe was first set at 45% of the average weight of EEE put on the market in 2016 and has been increased to 65% in 2019.

However, as shown on the Figure 4 below, in 2020 the total collection rate of WEEE barely reached the 2016 target.

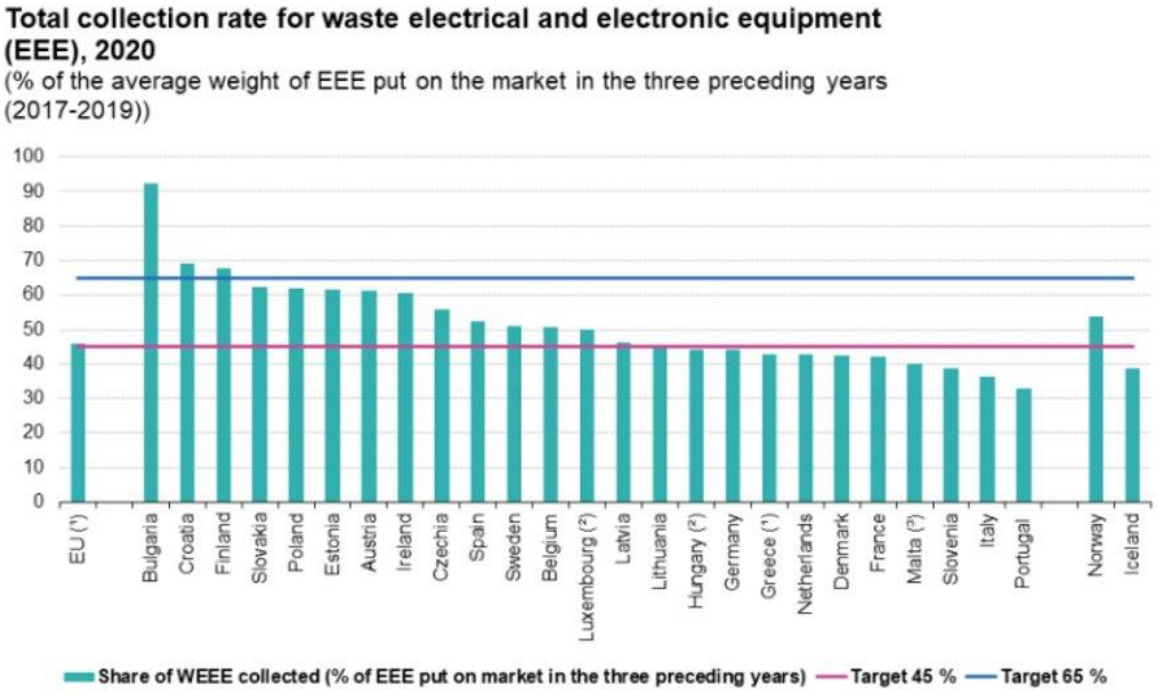

Figure 4: Total collection rate for WEEE in 2020

Some exemptions are not subject to the WEEE directives

- Equipment which does not require electricity for its primary function
- Equipment which is part of another type of equipment outside of the scope of the WEEE regulations
- Filament bulbs
- Household luminaires
- Equipment for military purposes
- Large scale industrial tools
- Implanted or infected medical equipment

As a medical device, SusFE product could be exempted from that directive.

4 Product

4.1 Medical Device

The objective of this project is to develop new medical devices adapted to human clinical studies and presenting essential ecological characteristics. Thus, when deploying such devices, it is necessary to pay special attention to

- Design of the product architecture
- System design engineering
- Medical device design and environmental regulatory standards

In this section, the focus will be on the 3 main standards around these medical devices.

MDR:
The Medical Device Regulation (MDR) is a comprehensive set of regulations developed by the European Union (EU) to ensure the safety and performance of medical devices while ensuring their compliance with environmental and ethical standards. It replaced the Medical Device Directive (MDD) and introduces new requirements for medical devices, including stricter clinical evidence requirements, a greater focus on post-market surveillance and increased transparency. The MDR aims to provide a higher level of protection to patients and users of medical devices, while promoting innovation and competitiveness within the medical device industry. It sets out clear requirements for manufacturers, importers, and distributors of medical devices to ensure that their products are safe, effective, and environmentally friendly. Overall, the MDR represents a significant step forward in the regulation of medical devices, strengthening the existing framework and enhancing patient safety while promoting sustainable development.

ISO13485:
ISO 13485 is an internationally recognized standard for quality management systems that specifically addresses the requirements for medical device manufacturers. It provides a framework for medical device companies to establish and maintain a quality management system that ensures the safety and efficacy of their products, while also promoting environmental sustainability. ISO 13485 covers all aspects of the product life cycle, including design, development, production, installation, and servicing. The standard also incorporates regulatory requirements, such as the EU's Medical Device Regulation, to ensure that medical devices meet all relevant regulatory and legal requirements. By adhering to ISO 13485, medical device manufacturers can demonstrate their commitment to producing safe and effective products, while also improving efficiency, reducing waste, and minimizing the environmental impact of their operations.

EC 60601-1:
EC 60601-1 is a safety standard for medical electrical equipment and systems that is recognized internationally. It is designed to ensure the safety of medical

equipment users and patients, while also considering environmental sustainability. The standard specifies general safety requirements for medical electrical equipment, including protection against electric shock, fire hazards, mechanical hazards, and other potential risks. EC 60601-1 also addresses the environmental impact of medical devices by requiring manufacturers to consider the life cycle of their products, from design to disposal. This includes minimizing the use of hazardous materials, promoting energy efficiency, and ensuring that products can be easily disassembled and recycled. By complying with EC 60601-1, medical device manufacturers can demonstrate their commitment to producing safe, effective, and environmentally sustainable products.

4.2 Eco-Design

The objective in this project is to identify the standardization and policies that apply to the products developed. But to go further, it is important to be aware of the draft regulations in progress in order to anticipate the definition of the various products. And to go even further, it is necessary to be heard by the institutions in charge of these draft regulations so that they are adapted to the vision we have but more broadly to the world in which we live.

It is in this context that BeFC was able to speak in a draft regulation on eco-design and the digital passport of objects. Here, the goal is to be fully involved in the regulations in force but also in the process of being drafted and those that will be published later.

BeFC has also held several exchanges with two French ministries in order to identify blocking points, opportunities and to fully collaborate so that the technology carried by BeFC as well as the products developed by the SusFE project have the greatest possible impact on our society.

However, there are already standards in place in Europe. The main one is the directive 2009/125/EC. It is an EU directive that aims to improve the energy efficiency of energy-related products sold in the European Union. It establishes ecodesign requirements and energy labelling requirements for products and requires conformity assessments to demonstrate compliance. The directive also establishes a framework for market surveillance to ensure compliance with the requirements. Its objective is to reduce the environmental impact of energy-related products and promote energy efficiency in the EU.

4.3 Circular Economy

The circular economy is an economic model that aims to keep resources in use for as long as possible by reducing waste, pollution, and the consumption of natural resources. It is a departure from the traditional linear economy, which relies on a "take-make-dispose" model of production and consumption. The circular economy emphasizes the importance of designing products that can be easily repaired, reused, and recycled, as well as the need to reduce energy consumption

and greenhouse gas emissions. The circular economy is becoming increasingly important in light of the challenges posed by climate change and resource depletion, and it has the potential to create new business opportunities and generate economic growth while reducing environmental impacts. This is why it is essential that the entire SusFE project is as circular as possible.

For this, BeFC has seized an important opportunity, we are part of the committee in charge of writing and deploying ISO standards around the circular economy.

It is a working group writing a package of standards to implement the circular economy, it is the ISO 59000 series.

This package of standards consists of : (Publication)
ISO 59004: terminology, principles and guidance for implementation (Q1 2024)
ISO 59010: guidance on business models and value networks. (Q1 2024)
ISO 59020: measuring and assessing circularity (Q1 2024)
ISO 59040: product circularity data sheet (Q4 2024)
ISO 59014 : principles, sustainability and traceability requirements (Q4 2024)

ISO 59004, focusing on terminology, principles and implementation guidelines, defines the circular economy as an economic system that uses a systemic approach to maintain a circular flow resources, by recovering, retaining or adding to their value, while contributing to sustainable development.

As for the principles :

Systems Thinking
- Long-term systems perspective
- Considering the impacts of interactions among environmental, social, and economic systems
- Life-cycle perspective of solutions

Value creation
- Recover, retain or add value
- Minimize extraction of non-renewable resources
- Manage renewable resources to recover, retain or add value over time.

Value Sharing
- Collaborate along the value chain or value network in an inclusive and equitable way

Resource availability
- Manage stocks and flows of resources to contribute to their availability for present and future generations
- Secure the quality and resilience of ecosystems

Resource traceability

- Manage and track stocks and flows of resources in a transparent and accountable way

Ecosystem resilience

- Implement practices that protect and contribute to the regeneration of ecosystems and their biodiversity
- Take into account planetary boundaries

Actions that create added value

- Circular design
- Circular sourcing
- Circular procurement
- Processes optimization
- Industrial symbiosis

Actions that contribute to value retention

- Reuse and redistribution
- Maintenance and servicing
- Performance-based approaches
- Sharing to intensify use

Actions that contribute to value recovery

- Refurbishment
- Remanufacturing
- Reverse logistics
- Cascading of materials
- Recycling
- Waste management

Actions that generate lost values

- Regeneration of ecosystems

Enablers -> Action to support circular transformation

- Education and research / Innovation / Collaboration and networks / Helping users change their behaviour / Policy and legal system / Investments

The ISO 590220 interested in Measuring and assessing circularity

The ISO 590220 standard provides a framework for organizations to measure and evaluate circularity, with a focus on contributing to sustainable development.

The measurement framework outlined in the standard includes monitoring circular actions such as rethink, reuse, reduce, repair, and recycle. The standard also emphasizes the need to measure flows, specifically conserving, regenerating, and creating them. Additionally, the standard requires assessing the impacts of sustainability, including social, environmental, and economic impacts.

Thus, it is necessary to conduct the project with all these components in mind, on the one hand to best comply with future standards but specially to develop the most virtuous products possible, whether on the economic, environmental and social levels.

4.4 End-of-Life

In Europe, the regulation of medical devices is governed by the Medical Device Regulation (MDR) and the In-vitro Diagnostic Medical Devices Regulation (IVDR). These regulations have specific requirements related to the end of life of medical devices.

According to the MDR and IVDR, medical device manufacturers are responsible for ensuring that their products are designed and manufactured in such a way as to facilitate their safe and environmentally sound disposal at the end of their life cycle. The regulations also require that manufacturers provide information to users on how to safely dispose of their products.

In addition to the MDR and IVDR, there are several European and international standards related to the end of life of medical devices. These include:

- EN ISO 15223-1: Medical devices -- Symbols to be used with medical device labels, labelling, and information to be supplied -- Part 1: General requirements. This standard specifies symbols to be used on medical device labels, packaging, and information to be supplied to facilitate safe disposal of the device.
- EN ISO 14971: Medical devices -- Application of risk management to medical devices. This standard provides a framework for managing risks associated with medical devices, including those related to end-of-life disposal.
- EN ISO 14001: Environmental management systems. This standard provides a framework for organizations to manage their environmental impact, including the management of waste generated by medical devices.
- EN 50625-2-3: Collection, logistics & treatment requirements for WEEE - Part 2-3: Treatment requirements for medical devices and monitoring and control equipment. This standard provides guidelines for the treatment of waste electrical and electronic equipment (WEEE), including medical devices and monitoring and control equipment.

Overall, these standards and regulations aim to ensure that medical devices are safely and environmentally soundly disposed of at the end of their life cycle.

5 Conclusion

Thus, through this report, an overview of the standardisation and policies around the products developed within the SusFE project has been made.

It is therefore necessary to clearly define and agree the terms we use. Moreover, there is a problem concerning the nature of the energy source. After an internal study and with different partners, the regulations dedicated to batteries apply to the product developed by BeFC.

For the electronic part of the product, there is a set of marking, conformity test and directive to frame the deployment of this type of electronics. Finally, other regulations come into play when considering the product as a whole, in particular concerning medical devices, eco-design, or the end of life of these products.

Finally, the whole project must be aligned with the principles of the circular economy so that the whole value chain is as virtuous as possible.