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FEMTOSURF Consortium

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1. Introduction

The main objective of FemtoSurf project is to develop, test and demonstrate industrial-grade solid-state 2-3 kW-level fs laser with parameters suitable for metal surface patterning applicable in industrial settings. FemtoSurf industrial-grade 2-3kW-level fs laser will be integrated in propose-built optical chain enabling multi-beam processing (100+ simultaneous beams) with individually tailored spatial distributions in each laser spot, integrated into a fully automated processing setup for efficient patterning arbitrary shaped metal components with sizes exceeding several meters while retaining micrometre level precision and on-the-fly quality assessment (zero faulty parts delivered).

Project description

Creating 3D patterns on surfaces changes their properties and the way they interact with other materials. Ultrafast lasers are proving particularly promising in this realm. Surface features on scales from nanometer to millimeter sizes can be controlled to fine-tune functionality and performance in numerous applications from aerospace to biomedicine with particular interest in wettability, attraction and repelling. The FemtoSurf project has a bold idea for these tiny patterns. The project partners are developing the technology to enable the simultaneous several beams of ultrafast laser beam for surface patterning. When integrated into an automated industrial setup, the system will enable patterning at the micrometer scale in components exceeding several meters in length. This technology will open the door to exciting possibilities to optimize aerodynamics in large structures such as planes, ships and implants.

2. FemtoSurf overview

2.1. Project overview

The FemtoSurf project is a 3-year project that has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant agreement #825512 and funded by one of the calls under the Photonics Public Private Partnership. The overall concept underpinning the project is the development of a system for the treatment of large surface areas using kW-level femtosecond (fs) laser for metallic surface nano- to milli-patterning for enhanced surface repelling and/or adhesion properties, leading to increased durability, self-cleaning, anti-fouling, or enhanced tissue attachment.

FemtoSurf is a multinational partnership between 9 consortium partners representing professionals from academia and industry, the laser researchers, material scientists, robotic systems designers, dental, ships, and aircraft manufacturers; the leading partner Femtika is responsible for providing the final report on standardization activities (deliverable D9.1 R) which is further outlined in the following document. The goal of the FemtoSurf consortium – represented by Femtika – is to obtain EU and market required standards and to approach standardization organizations, groups and Technical Committees on the matter of material processing using environmentally safe solutions, as well as undergo green labeling procedure.

2.1.1. IP management

Results in 5 areas will be available for each member of the Consortium for future research purposes. Exclusive rights will be left to one company that contributed the most to development of particular technology. There is one exception group (materials and surfaces of products), where research for companies is possible, excluding research in the dental field. In the table below lime colored cells mark the exclusive rights of a company for specific results, white cells show rights to use results for research, and grey cells show aforementioned exception for research in the dental field.

TABLE 1: RIGHTS FOR THE USE OF FEMTOSURF PROJECT RESULTS BY COMPANY (LIME COLORED CELLS – EXCLUSIVE, WHITE – RESEARCH NEEDS, GREY – RESEARCH OUTSIDE THE DENTAL FIELD)

RESULTS AND RELATED INTELLECTUAL PROPERTY RIGHTS	FEMTIKA	AMPHOS	SUPSI	RAMTEID	STRAUMANN	FORTH	HELIOTIS	ROLLA	AEREA	MTC
Surface treatment patterns and methods and Large-scale surface modifications[1]										
Large scale surface modifications[1]										
Design and development of automated femtosecond laser manufacturing cell										
FemtoSurf sensing system										
Materials and surfaces of products[2]										

1 – with kW level femtosecond laser technology

2 – including titanium, titanium alloys [such as Roxolid], zirconia, SLA, SLActive, etc. and any experimental materials or surfaces provided or otherwise disclosed by Straumann, its affiliates or partners

PATENTING ACTIVITIES | Exclusive owners of project results shall bear all costs and be responsible for the preparation, filing, and prosecution of any application for patents, designs, or other registration activities and shall have the right to choose the territorial coverage, scope, and other aspects of such application(s).

COMMERCIALIZATION | Femtika stands as a sole and exclusive representative of all the Parties to Commercialize the FemtoSurf machine, including, but not limited to, the manufacturing of the FemtoSurf machine.

Parties grant Femtika an exclusive license for background results and know-how needed to fulfill the commercialization of the FemtoSurf machine. This license includes the rights to Femtika to choose and appoint agents, sub-contractors, or other third parties for the commercialization of the FemtoSurf machine.

COMMERCIALIZATION PLAN | Femtika will prepare a commercialization plan within 6 months after the end of the grant and separately will discuss this topic with the members of the consortium representing different industries (as presented in the table below).

TABLE 2: DISCUSSION WITH CONSORTIUM MEMBERS BY THE COMMERCIALIZATION INDUSTRY

INDUSTRY	STRAUMANN	ROLLA	AEREA	MTC
Dental	+			

Maritime		+		
Aerospace and aircraft			+	
Tooling				+

The exception in the discussions will be the dental field due to its specifics. Further development, pre-clinical and clinical studies, and product registration is expected to take 4-5 years after the project termination.

When the plan for the corresponding industry is confirmed by the related company, Femtika can commercialize the machine in the respected industry. If no agreement is reached regarding the plan in six months after the end of the grant, then Femtika can commercialize the FemtoSurf machine at its sole discretion, except the dental field, where exploitation and commercialization rights go to Straumann and Femtika's license lapses.

2.2. Technology

The current situation pertaining to laser texturing machines is limited to step-and-scan solutions where the laser power and the precision of machines are limited. In FemtoSurf a novel femtosecond (fs) high power laser source will be designed and integrated, thus ensuring better performance in stability of the machine and therefore ensuring positioning precision.

The main objective is to develop, test, and demonstrate industrial-grade solid-state 2-3 kW-level fs laser with parameters suitable for metal surface patterning applicable in industrial settings. FemtoSurf industrial-grade 2-3kW level fs laser and optical chain enabling multi-beam processing will be integrated into a fully automated manufacturing cell for efficient patterning of variously shaped metal components with sizes exceeding several meters while retaining nanometer-level precision and on-the-fly quality assessment. The solution will include programmed patterning schemes for typical applications.

2.2.1. Surface treatment patterns research phase

Best-suited surface topographies for typical applications (medical tools, prosthesis, manufacturing tools, aerospace, and shipping equipment, etc.) will be programmed and included in the system relying on the existing scientific data with modeling and extensive research in material science (carried out by consortium partners FORTH and Femtika).

Initial experimentation was conducted with existing lasers that allows to check the patterning. During the testing stage, the patterns will be checked for meeting the industry performance standards.

At this phase, research for novel quality control methods was conducted by FORTH.

2.2.2. 2-3 kW-level fs laser

To meet the industry needs 2-3 kW-level average power fs laser is needed. Lasers of lesser average power are not capable of efficient parallelized manufacturing due to insufficient intensity. There is also

no replacement available for the technology Innoslab that uses Yb:YAG crystal satisfying 5 necessary technical criteria to reach the desired result: 1) relatively broad emission spectrum, 2) mechanical and chemical robustness, 3) small quantum defect (energy losses), 4) can be diode-pumped, 5) can be grown for specifications required for kW-level fs laser.

Consortium member Amphos has the technology that serves as a base for 2-3 kW fs laser development and will enable industrial-scale nano-to-millimeter patterning of surfaces to make them functional and obtain the desired properties.

2.2.3. Optical chain

For guiding and controlling the laser beam of 2-3 kW fs laser an optical chain must be designed. Femtika, the leader of the consortium is responsible for this task. The optical chain must satisfy 3 functional requirements: 1) split a single kW-level fs laser beam into multiple for parallel processing, 2) control spatial characteristics of each beam, 3) direct the radiation to the scanner head (where an observer can see a laser is coming from).

Besides the design of the optical components, Femtika's expertise in creating custom software for digital photonic component control serves as a base for highly advanced software needed to control the optical chain and the whole setup.

2.2.4. Robotic system (manufacturing cell)

The optical system will be integrated into an automated closed-loop manufacturing cell developed mainly by SUPSI. The manufacturing cell will include several critical technological elements: a laser machine head, vision system, a structure to ensure stability and robustness of the setup for smooth movement and vibration minimization, and a design for a safe and controlled environment.

LASER HEAD | The laser head is composed of a 3-axes laser scanner, a monitoring camera, and an auxiliaries box. The system is capable to create the laser volume necessary for the processes. The laser head must be placed on the machine and therefore a set of comprehensive constraints are given to achieve a successful integration (see Table 3).

TABLE 3: LASER HEAD REQUIREMENTS

REQUIREMENT	VALUE	UNIT
Dimensions, maximum	320 x 550 x 190	[mm]
Weight, maximum	30	[kg]
Working environment temperature	20 +/- 1	[°C]

The head includes elements to perform a full measurement for the geometry of processed part: the laser scanner for material processing, a 3D metrology scanner operating in the micrometer to millimeter scale, and a stereoscopic system with a thermal camera.

The multi-dimensional analysis will be performed during the process in a completely automated digital manner in a way that ensures that parts can be kept in the same referred position. The geometrical measurement will also be enhanced with a persistent closed-loop real-time laser beam quality control sub-system, based on sensors operating in the infrared and visible parts of the spectrum. Such sensors will be directly nested in the optical chain and will contribute to modulate the power and size of the laser beam.

VISION SYSTEM | The vision system is designed to recognize, at a micrometric level, the geometry of the part installed on the machine. For that, a set of cameras is adopted, mounted in a specific position with the related hardware. Also, for this component, a set of requirements must be fulfilled.

TABLE 4: LASER HEAD REQUIREMENTS

REQUIREMENT	VALUE	UNIT
Dimensions, maximum	260 x 515 x 200	[mm]
Weight, maximum	33	[kg]
Working environment temperature	20 +/- 1	[°C]

A large size robot equipped with a metrology solution operating in nano- to submicron scale will be running in tandem with the main machine. The nanoscale measurement will be performed to specific critical spots of the workpiece due to the high time consumption. The robot will enable the integration of a confocal metrology solutions. The robot size will ensure coverage of large components, i.e., propellers, or big batches of medium size parts, i.e., prostheses and tools.

SETUP | While the confocal metrology system will perform the actions, the robot will be kept steady with switched-on breaks and switched-off motors to ensure no vibrations or misplacements in the mechanical structure.

To connect the robot to the overall system, the FemtoSurf manufacturing cell will be integrated with a transportation system and two load/unload (LU) stations. The LU stations will present mechanical calibrated references enabling the accurate and stiff clamping of parts.

PROCESSING ENVIRONMENT | The overall solution will be encapsulated in a room with controlled properties with temperature and pollution sensors, and safety infrastructure, such as laser-safe glasses for the room windows and Atex panels of the structure.

2.2.5. Quality control unit

FemtoSurf solution includes persistent multi-scale monitoring of manufacturing processes and the working environment for flawless manufacturing. This will be carried by the sensing system collecting information to support the design phase of a final product that will target the desired performance parameters: the energy efficiency, product quality over time, throughput, and quality of the process. The overall goal will be achieved by fulfilling 2 objectives: 1) development of the sensing system architecture capable of the monitoring manufacturing process and quality of the parts, 2) design of

software and hardware infrastructure for the rapid sensor fusion - processing of heterogeneous multi-source data to pass it to the data fusion system and produce more consistent, accurate, and useful data.

2.3. Customers

Based on preliminary research and treated surface functionality, Femtika had recognized a total of 6 industry areas that could become the end-users of the technology: Shipbuilding, Medicine, Solar Cells, Aviation, heavy industry, and electrochemical oxygen evolution catalysis. However, after conducting more research during the project, analyzing relevant literature, and assessing the current use of laser-treated surfaces, Femtika identified osseointegration (medicine) and solar cells as the most promising and realistic fields to initially move forward with.

2.3.1. Osseointegration

Osseointegration is the scientific term for bone ingrowth into a metal implant. An artificial implant is permanently surgically anchored and integrated into the bone, which then grows into the implant. Osseointegration is mostly used in dental implants and joint replacement surgery. It has been very successful in these uses for decades.

DENTAL IMPLANTS | A dental implant is an artificial fixture in the jaw, which acts as a replacement tooth root. It is usually made from titanium. During the placement of an implant, the main aim is to achieve immediate close contact with the surrounding jawbone. After a period of healing, teeth implants become anchored and stable, thanks to osseointegration. This is a process whereby jawbone cells grow up to the implant surface to grip it securely. The implant is normally roughened or coated to increase the area available for osseointegration.

JOINT REPLACEMENT | Osseointegration is a surgical procedure that aims to offer a better quality of life and improved function and mobility to people who have had an amputation. Surgery involves inserting a metal implant into the bone of a residual limb, which then attaches directly to a prosthesis, eliminating socket-related issues. The ability of an implant to bond with the surrounding host bone is another fundamental requirement for permanent orthopedic implants. Insufficient osseointegration can lead to the formation of fibrous tissues and ensuing loosening of the prostheses.

The ultimate effectiveness of osseointegration depends on the surface topography of an implant. The properties of the implant's surface are crucial for adhesion and differentiation of osteoblasts during the initial phase of osseointegration as well as in long-term bone remodeling. Factors such as the design, chemical composition, surface roughness, and surface chemistry of the implants and loading conditions are important to ensure smooth osseointegration of implants.

These properties can be modified at a microscale by such manufacturing techniques as acid etching, grit blasting, machining, and sandblasting. These methods are intended to produce an optimal degree of roughness to promote osseointegration. Microscopic pits, grooves, and protrusions increase the surface area to act as a foothold to bone tissue and they set the stage for biological responses at the bone-to-implant interface. Surface topography matters also at the nanoscale, where it interacts with tissues at cellular and protein levels.

Sandblasting effectiveness is measured by surface roughness parameters while this is not what directly benefits biologically. Such structures are random and uncontrolled depending on particle sizes. Laser treatment, if replace the sandblasting, allows to have greater control of the surface features and improve repeatability.

The natural bone environment at the nanoscale level is made up of grains that are 10–50 nm in size and consist of mineralized osseous tissue. Smooth surfaces will cause the formation of a fibrous callus as part of the normal healing process after implantation. The fibrous callus will become calcified and remodeled into a bony callus. A fibrous callus is unwanted since it provides a boundary between the implant and bone and causes the implant to be much more loosely attached instead of being more directly incorporated into the bone. By mimicking the nanostructures of a healthy bone, this nanotopographical modification would lead to osteoblasts depositing calcium as if the implants were bony tissues meant to integrate the implant directly into the healthy bone tissues.

Another benefit of the laser method is its sterility: all organic molecules and contaminations are burnt away, there are no foreign particles or residue left.

The opportunity that FemtoSurf has is the ability to process and treat the implants in order to create the highly requested surface roughness and controlled surface topography on the nanoscale. The FemtoSurf solution would allow to directly tune the properties of titanium implants, including targeted induction of repulsion or adhering in designated areas of the implant. Therefore, FemtoSurf's solution will lead to a giant leap forward in the functionality and longevity of implants.

2.3.2. Solar cells

A solar cell, or photovoltaic cell, is an electrical device that converts the energy of light directly into electricity by the photovoltaic effect, which is a physical and chemical phenomenon. It is a form of photoelectric cell, defined as a device whose electrical characteristics, such as current, voltage, or resistance, vary when exposed to light. Individual solar cell devices can be combined to form modules, otherwise known as solar panels.

To increase the overall efficiency of photovoltaic systems, such as solar cells or modules, different laser surface treatments have been adopted.

Efforts to maximize light absorption efficiency with reduced thickness have been made. Surface texturing is one of the techniques used to reduce optical losses to maximize light absorbed. Currently, surface texturing techniques on silicon photovoltaics are drawing much attention. Surface texturing could be done in multiple ways. Etching a single crystalline silicon substrate can produce randomly distributed square-based pyramids on the surface using anisotropic etchants.

Recent studies show that c-Si wafers could be etched down to form nano-scale inverted pyramids. Multi-crystalline silicon solar cells, due to poorer crystallographic quality, are less effective than single crystal solar cells, but mc-Si solar cells are still being used widely due to fewer manufacturing difficulties. It is reported that multi-crystalline solar cells can be surface textured to yield solar energy conversion

efficiency comparable to that of monocrystalline silicon cells, through isotropic etching or photolithography techniques.

Another useful enhancement of solar cell surface is anti-icing patterning or enrichment of the surface with superhydrophobic property for the cells to be used in an appropriate environment, f.e. arctic climate or rainforest climate.

With increasing solar cells efficiency and endurability, FemtoSurf can complement directly into the success of the alternative energy sector and slower wearing of solar panels.

2.3.3. Other industries

According to analyzes made by Femtika, solar cells and osseointegration are industrial areas with high potential for application and feasible with FemtoSurf project results. Other considered industries that have potential, however requiring more research and resources, are heavy industry and aviation with the need of friction and wear reduction, and electrochemical oxygen evolution catalysis (used in submarines and commercial aircrafts) with its demand for more hydrophilic surfaces.

2.4. Business model

FemtoSurf's overall business strategy is to develop and manufacture the FemtoSurf solution, provide maintenance services and provide direct material processing. Their 3 key functions are:

SERVICE PROVIDER | FemtoSurf receives components that need to be processed, processes them and the owner of the products then moves on to utilize/distribute them for clients that are not able to outright purchase the machine.

SYSTEM PROVIDER | FemtoSurf sets up their technology adapted to the end-user needs at the place of component manufacturers so that manufacturers can do it on the spot. In addition to this, FemtoSurf ensures maintenance services, provides training and instructions to the employees and participates in R&D activities to provide individualized surface functionalization.

FULL MATERIAL PROVIDER | FemtoSurf purchases materials and surfaces on their own to process and then sells already functionalized products directly to the end-user or via distributors.

The initial composition of the functions and revenue streams are the following: FemtoSurf will generate profit from sales of the hardware (60 %) plus monthly support (20%) and direct material processing (20%).

3. Standardization overview

3.1. Innovation and standardization

Standardization has several definitions, for example, according to Regulation (EU) No 1025/2012 of the European Parliament and the Council on European standardization, the primary objective of standardization is the definition of voluntary technical or quality specifications with which current or future products, production processes or services may comply. Standardization can cover various issues, such as standardization of different grades or sizes of a particular product or technical specifications in product or services markets where compatibility and interoperability with other products or systems are essential.[1]

Standards and standardization play an important role in research and innovation – according to the Research Study on the Benefits of Linking Innovation and Standardization, they improve the process of research by providing common terminologies, harmonized methodologies, and comparability between research activities. Key conclusions about standardization in research and innovation:

- standards play a multiple, catalytic role in the innovation system;
- the catalytic role seems to be particularly important for market acceptance of technology-based innovation;
- those researchers who are not active in standardization have a lower appreciation of the benefits of participation in standardization activities;
- there are barriers on both sides to improving the links between the innovation and standardization systems;
- better connections and motivations are particularly needed to improve the flow of new knowledge into standardization;
- intellectual property rights and standards co-exist in an acceptable manner in most industry sectors;
- performance-related standards may be innovation-enabling for outcome-based regulations.[2]

3.2. Directions of standardization

Accordingly, to the study done by Technopolis Group on the contribution of standardization to innovation in European-funded research projects, there are two main ways in which organizations can address standardization:

- using standards as an input to the research or further processes;
- using standards as a means to codify and disseminate the results of the research.

[1] Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardization

[2] Optimat. 2014. "Research Study on the Benefits of Linking Innovation and Standardization" https://www.cencenelec.eu/research/news/publications/Publications/BRIDGIT-standinno-study.pdf

This document will look in more detail at the first version of the standardization, as this by now is a more relevant option for the further commercialization of the project. Later, the document will briefly describe the second version of the standardization in terms of its main aspects, application potential, and the main possible benefits.

According to the results of the previously mentioned study, where the survey of EU Framework Programme project coordinators was done, the majority of coordinators who used standards as an input to their FP projects indicated that this aspect was of high importance to the overall success of their projects.[3]

According to respondents, using existing standards brings significant benefits:

- improves understanding of the state of the art;
- improves technical knowledge within the consortium;
- improves the efficiency of project activities;
- improves the quality of outputs.

The standards often provide a starting "reference point" for the projects and ensure that project activities and outputs will be widely accepted, applicable and interoperable with existing systems and technologies. Most projects using standards in this way expect to see various market impacts as a result, including improved design and interoperability of products, wider use of recognized methodologies and processes, and faster / easier market access.[4]

3.3. Stakeholders in the standardization process

There are many organizations developing standards. Standard organizations do not create standards themselves, as the work is mainly done by experts from the relevant industries. Those organizations or standardization bodies have different classifications, but one version identifies the distinction between formal, industrial, and company standards.[5]

Formal standards will be analyzed further. This type refers to standards that are recognized by the governmental authorities and are made by formal standardization bodies or in exceptional cases standards development organizations.

Further described are the levels where formal standardization organizations are operating.

[3] Technopolis. 2013. "Study on the contribution of standardization to innovation in European-funded research projects". https://www.cencenelec.eu/research/news/publications/Publications/Study_Contribution_Standardization_Innovation_Final2013.pdf

[4] Ibid.

[5] European Commission. 2014. "How will standards facilitate new production systems in the context of EU innovation and competitiveness in 2025?"

3.3.1. National level

In general, each country or economy has a single recognized National Standards Body (further – NSB), which all have one of the following roles:

- publishing their national standards, which are developed via consensus in Technical Committees by experts coming from all stakeholder groups;
- representing their country in the recognized regional and international standard-setting bodies;
- holding a reference library of national, regional, and international standards;
- selling copies of standards.[6]

The standardization system in Europe is based on the national pillars, which are one-stop-shop for all stakeholders and is the main focal point of access to the concerted system, which comprises regional (European) and international (ISO) standardization.

3.3.2. Regional (European) level

There are several regional standardization bodies in the world. As the location of the company is in Europe, the focus will be on the European Standardization Bodies, however, there are other regional standard groups in the world, such as COPANT in Latin America, PASC in the Asia-Pacific region, or ARSO in Africa.

Officially recognized European Standardization Organizations:

- CEN (European Committee for Standardization) is an association that brings together the National Standardization Bodies of 34 European countries. CEN supports standardization activities in relation to a wide range of fields and sectors including air and space, chemicals, construction, consumer products, defense and security, energy, the environment, food and feed, health and safety, healthcare, ICT, machinery, materials, pressure equipment, services, smart living, transport, and packaging;
- CENELEC (European Committee for Electrotechnical Standardization) is responsible for standardization in the electrotechnical engineering field;
- ETSI (European Telecommunications Standards Institute) produces globally applicable standards for Information and Communications Technologies (ICT), including fixed, mobile, radio, converged, broadcast, and internet technologies.

3.3.3. International level

There are many international standards organizations, but mainly as international standards organizations are understood the three largest and well-established organizations:

- ISO (International Organization for Standardization) is an international standard-setting body composed of representatives from 165 NSBs. ISO covers standards in a wide range of areas;

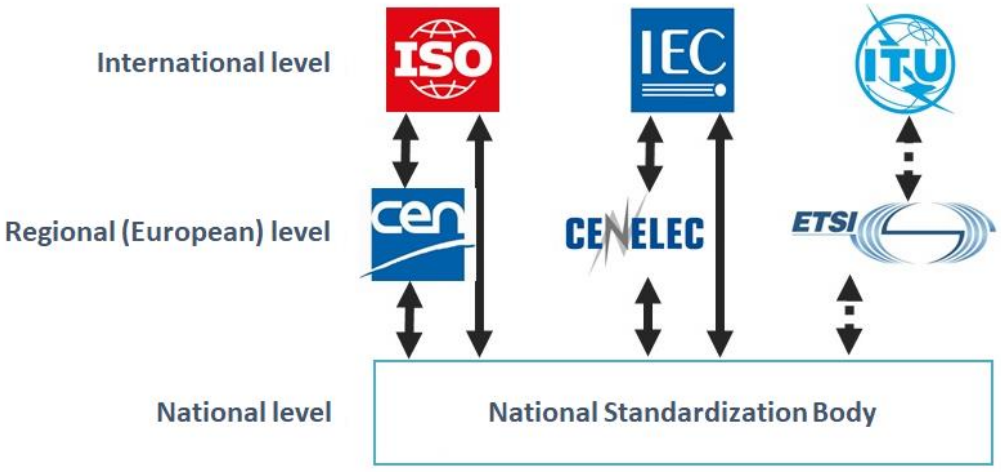
[6] Societal stakeholders and standards. https://www.standards4all.eu/index2.php#/lessons/Wu-V6wAfcQAdjX8Z1KJbYzwuRhf8D93f

- IEC (International Electrotechnical Commission) is an international standard organization that publishes standards in electrical, electronic, and related technology fields (electrotechnology);
- ITU (International Telecommunication Union) is an international standard organization that assembles experts from around the world to develop international standards in the field of information and communication technologies (ICT).

3.3.4. Interconnection between levels

An important thing to remember is that standards usually start at the national level. A simplified example of the structure of interconnection of standardization bodies is represented in Figure 1.

FIGURE 1: INTERCONNECTION BETWEEN FORMAL STANDARDIZATION LEVELS



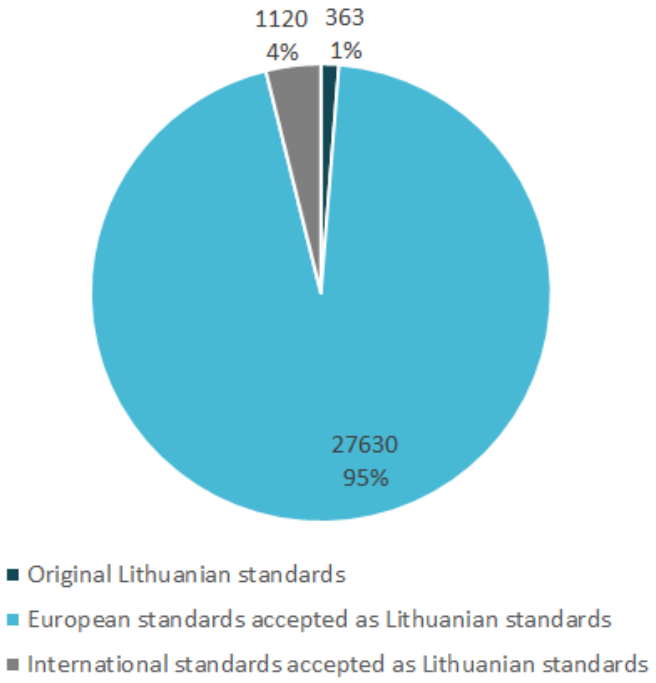
Source: adapted from LVS. Standardization structure. https://www.lvs.lv/page?slug=standartizacijas-struktura

As the telecommunications sector is not so relevant regarding this project, then ITU and ETSI will not be reviewed in more detail in the following sections. But it should be noted that interconnection is different than in the remaining two fields (ISO/CEN and IEC/CENELEC).

NATIONAL – REGIONAL (EUROPEAN) LEVEL | The NSBs play an important role in European Standard Bodies (CEN and CENELEC). They implement European Standards, translate, sell and distribute publications from European Standard Bodies, dispatch delegations to Technical Committees, Subcommittees, and Working Groups and participate in decision making on the technical, managerial, and political level.

Although NSBs can develop national standards themselves, the main role of NSBs and their technical committees is largely the development and approval of regional and international standards, which may then be adopted as national standards. This situation is well highlighted, for example, by the structure of the standards in force in Lithuania, as shown in Figure 2.

FIGURE 2: DISTRIBUTION OF STANDARDS IN BREAKDOWN TO PUBLISHING STANDARDIZATION BODIES

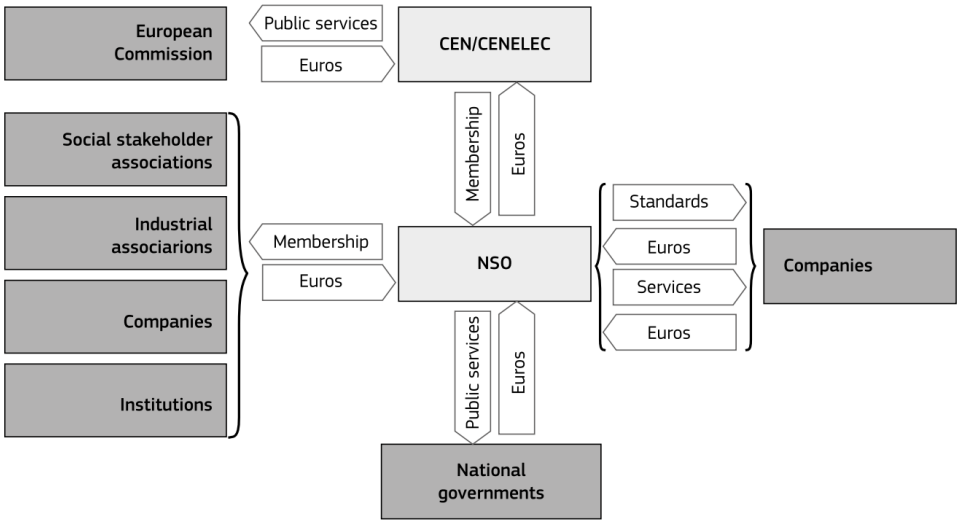


Source: adapted from LSD. STANDARTŲ RENGIMAS. https://www.lsd.lt/index.php?1548333462

It is the responsibility of the CEN and CENELEC National Members to implement European Standards as national standards. The NSBs distribute and sell the implemented European Standards and must withdraw any conflicting national standards.

The figure below shows the scheme of cooperation and financial flows between NSBs (defined in this figure as NSO), European Standard Bodies (CEN and CENELEC), and other stakeholders.

FIGURE 3: SCHEME OF STRUCTURE AND FINANCING OF NSOS AND CEN/CENELEC



Source: European Commission. 2014. "How will standards facilitate new production systems in the context of EU innovation and competitiveness in 2025?"

NATIONAL – INTERNATIONAL LEVEL | Members in international standards organizations (ISO and IEC) are representatives of the countries, normally their NSBs. All international standards are purely voluntary in application – even where a country has actively participated in the development and approval of International standards it is under no obligation to adopt it as a national standard.

REGIONAL (EUROPEAN) LEVEL – INTERNATIONAL LEVEL | CEN has an agreement with the ISO (Vienna Agreement) and CENELEC has an agreement with the IEC (Frankfurt Agreement), promoting the benefits of the international standards to international trade and market harmonization. The main objectives of those standards are to create a framework for the optimal use of resources and expertise in standardization and to ensure the mechanism for information exchange between the aforementioned standardization bodies.

The agreements operate in both directions, so international standards may be adopted by CEN-CENELEC, and standards developed in Europe may be offered to ISO or IEC and subsequently developed into international standards.

3.3.5. Other standardization/certification bodies

It should be noted that there are several other bodies responsible for certain standardization issues at different levels and in different fields, such as ITU (International Telecommunication Union), ETSI (European Telecommunications Standards Institute), ANSI (American National Standards Institute), ASTM (American Society for Testing and Materials), ECSS (European Cooperation for Space Standardization) and many others. If there are plans to operate in a particular market, or to focus more on a specific sector, the potential of such standardization bodies and the standards they provide should also be considered. Similarly, to demonstrate compliance with certain requirements, countries or

economic and political associations (such as the EU) may set out in regulatory acts the requirements that potential market participants must meet.

3.4. Standards regarding environment

Companies in the world are paying increasing attention to sustainability issues and environmental impact. Also, in this field, it is possible to use standardization and other tools to address these issues in business processes.

In general, there are several ways to implement green and sustainable principles, policies, and practices in companies, for example, by using green certificates and eco-labels. If FemtoSurf operating field is considered, standardization is the most suitable solution – ISO 14000 family standards are a widely used and internationally recognized solution in this field that sets out the criteria for an environmental management system. It maps out a framework that a company or organization can follow to set up an effective environmental management system. These standards are designed for any type of organization, regardless of its activity or sector. Out of this family of standards, ISO 14001 is the most widely used in the standardization of companies. It provides requirements with guidance for use that relate to environmental systems.[7]

Key benefits from the standardization that are identified by ISO 14001 users:

- demonstrate compliance with current and future statutory and regulatory requirements;
- increase leadership involvement and engagement of employees;
- improve company reputation and the confidence of stakeholders through strategic communication;
- achieve strategic business aims by incorporating environmental issues into business management;
- provide a competitive and financial advantage through improved efficiencies and reduced costs;
- encourage the better environmental performance of suppliers by integrating them into the organization's business systems.[8]

The potential for the use of this standard in relation to this particular technology is also demonstrated by the compliance of several manufacturers of similar technologies on the market with this standard. These examples, together with other standardization examples on the market, will be discussed in section 2.7.

3.5. Stakeholder analysis

Main stakeholders were identified regarding the standardization process. This list mainly consists of previously identified standard bodies in different levels. Their main goals were identified, as well as their roles in the Femtika standardization process.

[7] ISO. ISO 14000 family: environmental management. https://www.iso.org/iso-14001-environmental-management.html
[8] ISO. 2015. "ISO 14001: Key Benefits". https://www.iso.org/files/live/sites/isoorg/files/store/en/PUB100372.pdf

TABLE 3: IDENTIFIED STAKEHOLDERS IN STANDARDIZATION PROCESS

STAKEHOLDER	GOAL OF THE STAKEHOLDER	ROLE OF THE STAKEHOLDER IN THE PROJECT	LINK
ISO	Bring together a network of experts to share knowledge to develop and publish International Standards.	Developer of international standards in wide range of areas that are relevant to the project	https://www.iso.org/home.html
IEC	Prepares and publishes International Standards for all electrical, electronic and related technologies	Developer of international standards in electrical, electronic and related technological areas that are relevant to the project	https://www.iec.ch/homepage
CEN	Leading developer and publisher of voluntary European Standards and related products and services	Developer of European standards in wide range of areas that are relevant to the project	https://www.cen.eu/Pages/default.aspx
CENELEC	Prepares and publishes European Standards in the electrotechnical engineering field	Developer of European standards in electrotechnical engineering field that are relevant to the project	https://www.cenelec.eu/
National standards organizations	Develops and publishes national standards. Contribute to the development and approval of regional, and international standards, which may then be adopted as national standards	Developer of standards in a wide range of areas that are relevant to the project. Distributes international, regional and national standards.	e.g., NSB in Lithuania: https://www.lsd.lt/
Audit / certification institutions	Offers services related to the assessment and implementation of the requirements of specific standards	Allows to assess the existing situation regarding the implementation of standards, provides certification services	n/a

Source: CIVITTA analysis

3.6. Contribution to new standards

As mentioned before in this document, there are two main ways how organizations can address standardization. As the first option of using standards as an input to the research or further process was reviewed in more detail before, then the following section will shortly describe the main things about the second way – using standards as a mean to codify and disseminate the results of the research.

According to Standards and standardizations: A practical guide for researchers, one of the main reasons why this kind of standardization is used is that individuals and organizations can apply the information contained for their purposes. Standards are therefore first and foremost about applying the information contained for the benefit of the user, i.e., they specifically facilitate the dissemination and implementation of knowledge.[9]

In the previously mentioned study on the contribution of standardization to innovation in European-funded research projects, the main benefits in this option were also identified by the respondents:

- improved dissemination of project results;
- improved codification of new knowledge;
- improved opportunities to network and access complementary expertise.[10]

Once the new or revised standards have been published, various impacts on innovation in the marketplace are expected, including improved design and interoperability of products and services, easier and faster market access, and increased reassurance for consumers.[11]

[9] European Commission. 2020. "Standards and standardization: A practical guide for researchers"
[10] Technopolis. 2013. "Study on the contribution of standardization to innovation in European-funded research projects". https://www.cencenelec.eu/research/news/publications/Publications/Study_Contribution_Standardization_Innovation_Final2013.pdf
[11] Ibid.

Overall, the possibility of standardization depends on the project. In some cases, patenting of the output should be considered. To determine which options suit better for the product, it should be identified if the output under consideration is based on a clearly identifiable "inventive step". If such a step can be identified and it is considered that the financial benefits of protecting the invention significantly outweigh the costs of protecting it then it clearly makes sense to adopt the patenting route. However, in cases where there is no clear inventive step or where the inventive step is not deemed to have sufficient commercial potential to make the costs of patenting and patent protection viable, then the standardization route could be considered. [12]

3.7. Competitor analysis

There are a few research projects in the femtosecond laser field financed under the Horizon 2020 framework. Projects were analyzed to reveal potential competition. 2 projects were found to have competing industry applications: LubiSS in less amount, and Laser4Surf particularly competing in applying laser treatment for dental implants.

[12] European Commission. 2020. "Standards and standardization: A practical guide for researchers"

TABLE 4: COMPETITORS IN RESEARCH AND DEVELOPMENT

COMPETITOR	DESCRIPTION	TECHNOLOGY	FOCUS	INDUSTRY APPLICATION	CERTIFICATES
LAMpAS	H2020 Technology inspired by natural surfaces	High-power 1.5kW ultra-short 1-3ps pulse duration laser New optical concepts (reduced spectral bandwidth to at least up to 1.0 nm)	Anti-bacterial patterning Anti-fingerprint	Game tools Milk buckets	No/Unknown
LiNaBioFluid	H2020 research project on Biomimetic surfacing	Specific topography (patterning) of bark bugs and moisture harvesting lizards	Surface treatment R&D	Lubricant's friction and wear reduction	No/Unknown
LubiSS	H2020 project exploring potential of lubricant impregnated surfaces	-	Anti-icing Easy-to-clean Anti-fouling	Environmental Industrial Medical	No/Unknown
Laser4Surf	H2020 EU-funded research project for mass productio of functionalized metal surfaces	Integrated laser texturing prototype: Laser texturing device In-line monitoring system Simulation tools	Functionalities	Advanced batteries Linear encoders Medical components (dental implants)	No/Unknown
LASER4FUN	H2020 Research project	Patterning methods Laser-material interaction	Functionalities: Tribology Aesthetics Wettability	Laser surface engineering	No/Unknown

TresClean Project	H2020 project developing high throughput surface texturing for fluid-repellen and antibacterial metal surfaces	High-average power ultra-short pulsed lasers High performance scanning heads	Fluid-repellent Anti-bacterial	Food industry Home appliance (dishwasher)	No/Unknown

Source: CIVITTA analysis, projects' website

To picture femtosecond laser manufacturers' inherent standards, certificates, and stated compliance information about competitors from 9 different countries was gathered. The table below contains analyzed competitors.

TABLE 5: FEMTOSECOND LASER MANUFACTURERS AND SERVICE PROVIDERS

NAME AND WEBSITE	COUNTRY OF ORIGIN	DESCRIPTION, APPLICATION	CERTIFICATION & COMPLIANCE
Amplitude amplitude-laser.com	France	Laser systems provider for manufacturing (consumer electronics, semiconductors, etc.), medicine (ophthalmology, proton therapy, X-Ray imaging, etc.) and scientific research	Production center certified by **ISO 13485:2016** and **ISO 9001:2015**
Toptica toptica.com	Germany	(Multi-)Laser systems and system elements provider	**ISO 9001:2015 certificate** **ISO 14001:2015 certificate** **CE compliance** (European Economic Area) **RoHS compliance** (EU) **CDRH compliance** (USA)
Light Conversion lightcon.com	Lithuania	One of world leaders in femtosecond laser production	**ISO 9001:2015 certificate** **RoHS compliance** **REACH Statement** (EU) **Conflict Minerals Statement (USA)** **Green Energy**
EKSPLA ekspla.com	Lithuania	The company is leading in the global market for scientific picosecond lasers. The main products are femtosecond, picosecond and nanosecond lasers, industrial ultrafast lasers. Applications: Laser spectroscopy, Biomedical, Material processing, etc.	**ISO 9001:2015 certificate**
Lightmotif lightmotif.nl	Netherlands	Service provider: Micro-milling, Surface Texturing, Mold texturing, Systems for R&D or small-scale manufacturing	Unknown

NAME AND WEBSITE	COUNTRY OF ORIGIN	DESCRIPTION, APPLICATION	CERTIFICATION & COMPLIANCE
		Functionalities: Tribology, Wetting, Reduction of friction, Decorative	
VALO Innovations GmbH valo-innovations.com	Germany	Lasers for: life science (biophotonics/ multiphoton microscopy), neuroscience (optogenetics), nano- and micro material processing	No
KMLABS kmlabs.com	USA	R&D and production	Unknown
NKT Photonics nktphotonics.com	Denmark	Laser, fiber and optic sensing systems	**NKT Photonics – ISO 9001:2015 certificate** **Fianium – ISO 9001:2015 certificate** **NKT Photonics Switzerland – ISO 9001:2015 certificate** **NKT Photonics Switzerland – EN ISO 13485:2016 certificate** **CE Mark – Declaration of Conformance for EMI and Safety (EEC)** **Standards regarding safety:** • **BS EN 60825-1:2014 (laser class 4)** • **BE EN 61010-1:2010** • **BS EN 61326-1:2020**
FYLA fyla.com	Spain	Fiber laser architectures	Unknown
Laser Quantum laserquantum.com	UK	Lasers	**EN ISO 9001:2015** certification Developing **ISO 14001:2015** certification *Quote*: "Our lasers themselves are designed to comply with all applicable **National Compliance** obligations, European Directives on **RoHS** and **WEEE**, and other international compliance obligations such as **Conflict Minerals** reporting."

NAME AND WEBSITE	COUNTRY OF ORIGIN	DESCRIPTION, APPLICATION	CERTIFICATION & COMPLIANCE
Novanta (mother-company of Laser Quantum) novanta.com	UK	Trusted technology partner to medical and advanced industrial original equipment manufacturers	**Conflict Minerals compliance,** **RoHS, REACH,** **Human Trafficking and Slavery compliance** Require from sellers (laser suppliers): "**ISO 9001 standard** or an equivalent certification" and "where appropriate, quality management systems such as **ISO 13485**"
MPB Communications mpbcommunications.com	Canada	Fiber lasers, network-ready telecom solutions, amplifiers, data center interconnect, etc.	Certified **Women's Business Enterprise**

Source: CIVITTA analysis, companies' websites

3.8. Standards analysis

Typical standards from the analyzed industry were classified and put in a Table 6.

Standards were divided into groups: National, and groups of broader scope: Quality Management, Environmental, Laser-specific, Integrity-driven, and Industry-specific.

Based on the analyses of competitors, there was marked whether the standard requires certification or can be claimed to comply with by the company after implementing the required standardization and integrating appropriate operations.

There was marked geo-political scope where the standard originated and required to operate or is valued the most (e.g., INT - internationally, EU or the USA). Some standards might be relevant in the case of distributing the product to a specific market, e.g., the USA. They would all benefit the company brand image but be prioritized by the relevant geography first.

A description of when the standard is applicable was added in the column "When needed" (sometimes there are tech specifications, Femtika should comply with the standard or an alternative if the final product falls under the criteria) with a short description of the standard.

TABLE 6: STANDARDS CLASSIFICATION AND DESCRIPTION

GROUP	CERTIFICATE | STATEMENT	NAME	SCOPE	WHEN IS IT NEEDED?	SOURCE	DESCRIPTION
National	According to the national law	National compliance	LT	To manufacture in Lithuania	Lithuanian legislation	Compliance with Lithuanian laws
Quality management	C	ISO 9001:2015	INT	When an organization: a) needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and b) aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.	ISO	Standard for quality management system of an organization. All the requirements of ISO 9001:2015 are generic and are intended to be applicable to any organization, regardless of its type or size, or the products and services it provides.

GROUP	CERTIFICATE | STATEMENT	NAME	SCOPE	WHEN IS IT NEEDED?	SOURCE	DESCRIPTION
Environmental	C	ISO 14001:2015 (More advanced: ISO 14004:2016)	INT	Intended for use by an organization seeking to manage its environmental responsibilities in a systematic manner that contributes to the environmental pillar of sustainability. Applicable to any organization, regardless of size, type, and nature, and applies to the environmental aspects of its activities, products, and services that the organization determines it can either control or influence considering a life cycle perspective.	ISO	Standard for environmental management system of an organization. ISO 14001:2015 does not state specific environmental performance criteria. It can be used in whole or in part to systematically improve environmental management. Claims of conformity to ISO 14001:2015, however, are not acceptable unless all its requirements are incorporated into an organization's environmental management system and fulfilled without exclusion.
	S	WEEE Directive (Compliance)	EU	In the case of disposal of electrical and electronic equipment	Directive 2012/19/EU	Directive on Waste electrical and electronic equipment (disposal of equipment).
	S	RoHS Directive (Compliance)	EU	'Electrical and electronic equipment' or 'EEE' means equipment which is dependent on electric currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents and fields and designed for use with a voltage rating not exceeding 1000 volts (AC) and 1500 volts (DC).	Directive 2011/65/EU	Restriction of the use of certain hazardous substances in electrical and electronic equipment.

GROUP	CERTIFICATE | STATEMENT	NAME	SCOPE	WHEN IS IT NEEDED?	SOURCE	DESCRIPTION
	S	EMC Directive	EU	In the case of usage of electrical equipment or electronic equipment, which can emit electromagnetic waves, as well as equipment being affected by undue Electromagnetic Interference (EMI) from other apparatus.	Electromagnetic Compatibility Directive 2014/30/EU	In accordance with the LVD & EMC Directive, the product shall be submitted to the testing laboratory for carrying out the certification procedure. The notified body shall issue the CE Certificate to the manufacturer upon receiving positive test results and after examination of documentation.
	S	Low Voltage Directive (LVD)	EU	In the case of usage of electrical equipment operating with a nominal voltage between 50 and 1000 V (AC) and between 75 and 1500 V (DC).	Low Voltage Directive 2014/35/EU	In accordance with the LVD & EMC Directive, the product shall be submitted to the testing laboratory for carrying out the certification procedure. The notified body shall issue the CE Certificate to the manufacturer upon receiving positive test results and after examination of documentation.
	S	REACH (certificate / compliance)	EU	When using one of the substances (chemicals) enlisted in the Regulation annex and/or buying them from outside the EU/EEA. It could be a self-declaration, or a certificate can be received.	Regulation (EC) No 1907/2006 -> Annex XIV	To comply with the regulation, companies must identify and manage the risks linked to the substances they manufacture and market in the EU. They must demonstrate to ECHA how the substance can be safely used, and they must communicate the risk management measures to the users. Example: *"LIGHT CONVERSION products are identified as „articles"(defined in REACH Article 3.3) and do not release any substances under their foreseen normal use. Suppliers of articles must provide recipients with information on Substances of Very High Concern (SVHC) if those are present above a concentration limit of 0.1% on an article*

GROUP	CERTIFICATE | STATEMENT	NAME	SCOPE	WHEN IS IT NEEDED?	SOURCE	DESCRIPTION
						level. LIGHT CONVERSION products do not contain any of 209 currently listed SVHCs".
	S	Green Energy Statement	INT	If a company uses energy from alternative sources.	Environmental integrity	If practiced, shows the company's value to sustainable development. Example statement: *"the Firm is increasingly focused on advancing the development of renewable energy sources through its purchasing practices. From 2016, 100% of electrical energy used in our company is from renewable sources"*
Laser-specific	C	IEC 60825-1:2014	INT	Applicable to safety of laser products emitting laser radiation in the wavelength range 180 nm to 1 mm	IEC	Safety of laser products. When obtained, is accepted to comply with US FDA CDRH rules: Laser Hazard FDA Class IIIb ~ IEC 60825-1:2014 3B class.

GROUP	CERTIFICATE | STATEMENT	NAME	SCOPE	WHEN IS IT NEEDED?	SOURCE	DESCRIPTION
	C	IEC 61010-1:2010	INT	If the following types of electrical equipment and their accessories included into the FemtoSurf machine: a) Electrical test and measurement equipment b) Electrical industrial process-control equipment c) Electrical laboratory equipment	IEC	Safety requirements for electrical equipment for measurement, control, and laboratory use
	C	IEC 61326-1:2020	INT	Requirements for immunity and emissions regarding electromagnetic compatibility (EMC) for electrical equipment, operating from a supply or battery of less than 1000 V (AC) or 1500 V (DC) or from the circuit being measured	IEC	Electromagnetic immunity IEC 61326:2020 specifies more detailed test configurations, operational conditions, and performance criteria for equipment with test and measurement circuits (internal or, external to the equipment, or both) that are not EMC protected for operational and/or functional reasons, as specified by the manufacturer. The manufacturer specifies the environment for which the product is intended to be used and selects the appropriate test level specifications of IEC 61326-1:2020.
	S	CDRH (Compliance)	USA	To sell in the USA, FDA CDRH compliance program: "Inspection and Field Testing of Radiation-Emitting Electronic Products" # 7386.001	USA FDA	Interchangeable with IEC 60825-1:2014 FDA Center for Devices and Radiological Health regulate the manufacture of radiation emitting electronic products

GROUP	CERTIFICATE | STATEMENT	NAME	SCOPE	WHEN IS IT NEEDED?	SOURCE	DESCRIPTION
Integrity-driven	S	Conflict Mineral Regulation	EU/ USA	To reveal integrity of the company	EU – the Conflict Minerals Regulation / Dodd-Frank Act	Policies ensuring all the supply chain elements avoid Conflict Minerals use. It is based on the US SEC Dodd-Frank Act, and active in the EU since Jan 1, 2021. EU companies used to state compliance with Dodd-Frank Act and yet little instances of EU-regulation compliance statement exist. Example statement: "*The Firm expects its suppliers to source materials from socially responsible suppliers.* *The Firm expects all its suppliers to comply with the Dodd-Frank regulation.* *Suppliers must pass this requirement through their supply chain and determine the source of specified minerals.* *Based upon the declarations of our suppliers and current information provided by them, we confirm that all products that are produced and distributed by the Firm do not contain "conflict minerals" as defined by Section 1502 of the Dodd-Frank Financial Reform & Consumer Protection Act.*"
	S	Anti-Human Trafficking and Slavery Statement	INT	To reveal integrity of the company	UN, National law	Policies ensuring all the supply chain elements not be subjected to human trafficking and slavery. Example statement: "*The Seller will at all times comply with and the Seller hereby represents that it does comply with all applicable United Nations and national laws, statutes, ordinances, rules, regulations, orders, and other requirements,*

GROUP	CERTIFICATE | STATEMENT	NAME	SCOPE	WHEN IS IT NEEDED?	SOURCE	DESCRIPTION
						regarding child labor, slavery and/or human trafficking".
Industry specific	C | S	ISO 13485:2016	INT	When manufacturing or treating medical devices. [NB]: If treatment of medical devices is not expected to be a major revenue stream of treatment revenue stream (20% expected of total revenue), then it is not the 1st priority certificate. However, working with medical devices is one of the fields where certification gives a significant credit to the company in the face of clients.	ISO	Requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. Such organizations can be involved in one or more stages of the life cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities

Source: CIVITTA analysis, official standards descriptions

3.9. Standardization example of ISO management system standard

According to a capibizO, management consultant company specialized in ISO certification, a universal framework to walk from nothing to a certified standardization can be divided into 8 stages. This framework should also be relevant for other similar standards and certifications. Worth mentioning that an additional step after receiving a certificate from a certificating body is certificate renewal. For instance, the ISO 9001:2015 certificate requires reassessment by the certification body every 3 years. If Femtika sustains standardized procedures, only steps 6 to 8 should be repeated to maintain certification.

FIGURE 4: ISO CERTIFICATION PROCESS

Source: capibizO

4. Standardization roadmap

Femtika will have to comply with standards and, in some cases, receive certificates of standards for service provision in laser treatment, quality management, etc. Depending on a standard it can be applied during different stages of technology readiness level (TRL).

4.1. Standardization regarding production

2 cases influence Femtika's activities regarding standardization: establishment of own production center or finding a subcontractor competent for manufacturing of FemtoSurf system.

OWN PRODUCTION CENTER | In the case of establishing their own production center, all the standardization will be undertaken by Femtika. Advice may be sought from consortium members regarding certificates already received: Aerea has an ISO 9001:2015 certificate regarding quality management, MTC and Straumann might have received certificates related to the manufacturing process or environmental matters.

There will be necessary to develop an investment plan and attract investments or credits. Such an option ensures lower risks for intellectual property leakage and lower long-term costs for production than by paying a fee to an external manufacturing center. As for investments, it is worth considering both bank loans and private investments. For private investments possible option is seeking investments from consortium members who are going to use FemtoSurf machine.

MANUFACTURING SUB-CONTRACTOR | In this case, most of the standardization activities can be delegated to a sub-contracting body, moreover, it is possible to choose one which already has received certificates of quality management (ISO 9001:2015) and environmental management systems (ISO 14001:2016) and implemented compliance with WEEE Directive.

Using services of a sub-contractor capable to produce FemtoSurf is another option. This case does not need instant investments and has such benefits as lower initial costs, lower business risks, and faster start of production. Cons of the option are intellectual property leakage and higher long-term production costs.

4.2. Implementation of standards

Based on the competitor analysis conclusions regarding necessity of standards were made and presented in the table 7. Further in the section will be presented ability to receive standard certificates or make respective statements depending on the TRL.

TABLE 7: STANDARDS BY NECESSITY, ORDERED BY PRIORITY

GROUP\PRIORITY	MUST-HAVE	DISTINCTIVE ADVANTAGE	REPUTATIONAL BENEFITS	ON-DEMAND
National	National standards			
Quality management	ISO 9001:2015 certificate (majority of competitors have it)			
Laser-specific		IEC 60825-1:2014 IEC 61010-1:2010 IEC 61326-1:2020		CDRH Compliance Statement (exporting to the USA)
Environmental	RoHS Directive Compliance (must be checked for compliance, 10 elements are there) REACH Regulation Compliance (if there is usage of regulated chemicals) LVD & EMC Directive (must be checked if and which is applicable)		ISO 14001:2015 certificate WEEE Directive Compliance Recycling Statement Green Energy Statement	
Integrity	EU-Conflict Minerals Regulation Compliance		Anti-Human trafficking and Slavery Statement	
Industry specific				ISO 13485:2016 certificate (producing/ treating of medical tools)

Source: CIVITTA analysis

Femtika can start the standardization process and receive certificates depending on the TRL, and in some cases disregarding TRL. The scheme below matches development stages with standardization.

FIGURE 5: MATCHING STANDARDS AND TECHNOLOGY READINESS LEVELS

0	**Idea** Unproven concept, no testing performed	**IDEA**	**ISO 9001** and **ISO 14001** can be adopted by organization disregarding development of a particular product. **Anti-Human trafficking and Slavery** Statement can be done by the company disregarding product, when respective policies are integrated.
1	**Basic Research** Needs described without evidence		
2	**Technology formulation** Concept and applications formulated		
3	**Needs validation** Initial "offering" is developed and approved by stakeholders		
4	**Small Scale Prototype** Built in a laboratory environment (draft prototype)	**PROTOTYPE** (FemtoSurf is here)	After all material components of FemtoSurf system are identified, following compliance with following acts can be developed: **RoHS Directive** **REACH Regulation** **EU – Conflict Minerals Regulation** **EMC Directive** **LVD** (if relevant)
5	**Large scale prototype** Tested in intended environment		
6	**Prototype system** Tested in intended environment, close to expected performance	**VALIDATION**	After the prototype was developed, it is possible to apply for safety and immunity certificates related to lasers and measurement equipment: **IEC 60825-1:2014** **IEC 61010-1:2010** **IEC 61326-1:2020**
7	**Demonstration system** Operating in intended environment at pre-commercial scale		
8	**First of a kind commercial system** All systems and tech processes are ready to support commercial activity	**PRODUCTION**	On the stage of production planning, ensure compliance with **WEEE Directive** After ensuring commercial success (break-even) consider complementing to reputation by implementing better **recycling** practices and use of **green energy**.

Source: CIVITTA analysis, Horizon2020 annex G "Technology readiness levels" in work programme, CloudwatchHUB

4.3. Conclusion

As the best practitioners in the industry can be considered Novanta (the UK), NKT Photonics (Denmark), and Light Conversion (Lithuania, Femtika partner). Based on their example and broader industry and competitors' analysis were developed recommendations for Femtika.

WE HAVE IDENTIFIED 6 GROUPS OF STANDARDS	CONCLUSIONS	RECOMMENDATION
National	• Femtika should already have experience satisfying Lithuanian national standards required by law.	Consult a responsible expert in national laser-system-related standards who ensured compliance of available Femtika products so far.
Quality management	• Adopted by most of the identified competitors worldwide. Valued and widespread in most of the top economies. • Quality management implementation in any form is more important than receiving a certificate. ISO 9001 standard is designed to help organizations to be more efficient and more successfully meet the needs of their customers, thus the standard will benefit Femtika. • If quality management standard ISO 9001 is adopted correctly, the respective certificate would be easily received and bring both quality and reputational benefits.	Make sure the production center/sub-contractor has ISO 9001:2015 certificate or proper Quality Management System. Increase Femtika operations efficiency and customer satisfaction through complying with ISO 9001 and receiving ISO 9001:2015 certificate.
Laser-specific	• Rarely received by competitors. • Assure the safety of laser equipment and safety and performance of measurement equipment. • Can distinguish FemtoSurf among competitors.	Receive certificates when FemtoSurf already proves to be commercially successful to increase reputation. Check whether FemtoSurf satisfies these standards and state compliance even without applying for a certificate.
Environmental	• RoHS directive is mandatory in the EU. • Might be important for selling FemtoSurf to manufacturing giants and other companies caring for their brand identity. • Show company's commitment to sustainable development.	Check whether chemicals in the RoHS statement applicable to FemtoSurf production. If yes, comply with it. Check and adjust processes to comply with WEEE Directive and with CE marking requirements. Register CE, it is free. Check whether FemtoSurf production is easy to comply with ISO 14001, then adjust and state the compliance. The certificate is optional to increase the company's reputation.

Integrity	• Might be important for selling FemtoSurf to companies having the same statement as such standards apply to the stating company as well as to partners of that company. • EU-Conflict Minerals regulation is more universal than US Dodd-Frank regulation.[13]	Ensure supply chain audit not to include "conflict" minerals in the production of FemtoSurf system and not to include suppliers suspected of Human Trafficking and Slavery.
Industry-specific	• Not relevant while the business model includes little treatment of ready products by FemtoSurf. • The most important in the Medical field.	In case treatment of ready products for some industry by Femtika becomes an important revenue stream, think about complying with the respective standard and applying for a certificate to attract even more clients or hold existing.

Source: CIVITTA analysis

[13] https://learningcenter.sourceintelligence.com/blog/eu-conflict-minerals-comparison