1.1 Executive Summary

SFERA is a successful, 2-year long project in the area of laser-marking technology. It is pan-European in practice, as 9 companies from 4 countries were involved, and it is global in reach, as its results can be used by companies throughout the world.

The objective of the project was to develop a new laser-marking system that addressed all issues related to the marking of containers, their flow through production processes, and effective traceability and anti-counterfeit measures.

These issues include: marking containers without subsequent micro-cracks or contamination; readable marks enabling proper and rapid redirection of containers in production; identifying products throughout the supply chain; authenticating products to reduce the risk of counterfeit products entering the market.

SFERA developed a laser-marking system that has been proven to resolve all of these issues.

Target markets are the industries of: pharmaceutics; cosmetics and perfumes; luxury goods; beverage; automotive; photovoltaic modules.

SFERA can conceivably become a global standard in laser-marking technology, as potential clients are themselves global producers.

1.2 Project Description

SFERA is a co-operative research project of the Seventh Framework Program of the European Union, involving 9 SMEs from 4 countries, and spanning 2 years.

The SFERA project created a complete traceability and anti-counterfeiting solution by developing a new Sub-surface, Fast internal Engraving and Reading system suitable for Anti-counterfeiting applications.

Counterfeiting is a major global problem, with important societal and economic consequences, including the expansion of organized crime, loss of jobs and tax revenues, as well as serious health and safety risks, to which the pharmaceutical sector is particularly vulnerable.

Other issues of concern were anti mix-up of products during production, contamination from existing marking systems of containers, and cracking of containers from present engraving systems.

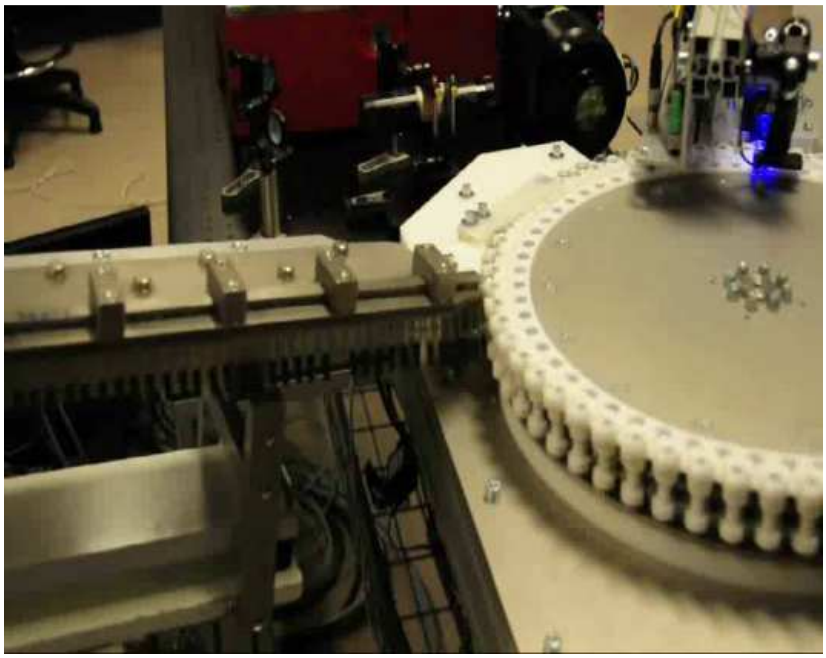
SFERA builds on the successful NAGINELS project, supported by the European Commission under the sixth framework program. During this latter program, an innovative process allowing internal engraving of transparent materials with no damage, micro-cracks, or contamination has been developed. Direct engraving of products with this technology linked with diffractive designs, coding and vision systems provides a full Track and Trace solution. The process developed is well suited to luxury applications, but does not yet meet the requirements of the pharmaceutical industry. Furthermore, no suitable on-line high speed reader is commercially available today for the invisible engraved codes.

1.3 Work carried out and Results

The engraving system developed during the SFERA project builds on a number of breakthrough technologies, to provide marking speeds suitable for the needs of the pharmaceutical industry, as well as applications requiring large area processing. Among the components specifically developed during the project are:

- A new, high average power, fiber-based ultrafast laser
- A high speed, portable reading system, suitable for fast identification of visible and invisible codes.
- A high speed beam delivery system, suitable for short process time.
- A high speed handling system, specifically designed for integration in production lines.
- A specific process control and encryption model for full and secure traceability and identification.

These components have been integrated in an industrial workstation, compatible with the requirements of the pharmaceutical industry.



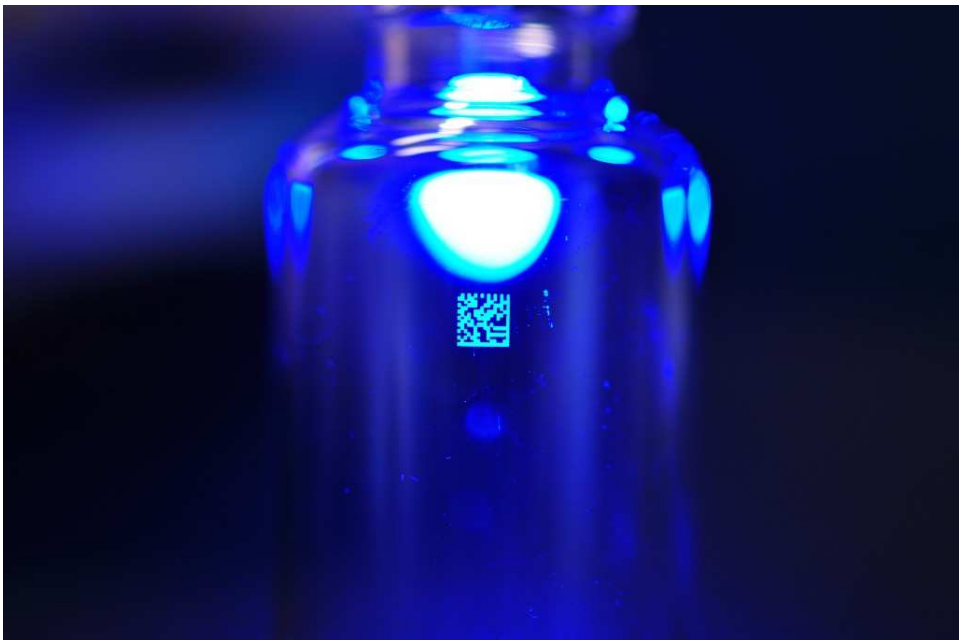
Industrial marking system, 10 syringes/sec.

The partners involved in the project are Trackinside, a Belgian company specialized in the marking of transparent materials for traceability and anti-counterfeiting markets, UK based Total Brand Security, Italian brand protection company Solos, French printing and engraving company Costet, French laser company Amplitude Systemes, Belgian laser application company LASEA, industrial integrator KST, mechanical engineering company EVILO, and French technology center Alphanov.

In addition, and Industrial Advisory Board, comprising major actors of the pharmaceutical industry, is associated with the project.

Main features of the engraving system are:

- Short process time, as low as 0.07 s
- Low code check time, as low as 0.07 s
- High surface engraving speed, up to 10mm²/s
- High scanning rate with low track error, up to 2 MHz.
- High efficiency reading system, both in reflection and transmission.



Example of a datamatrix internally marked in a pharmaceutical vial

For cosmetic and decoration applications, we benefit from a patented diffractive effect which combines anti-counterfeiting, traceability and a surprising rainbow pattern in the mark.

Internal engraving on a perfume bottle

During the project, an additional result achieved was the possibility of marking readable codes in reflexion, easing the integration of the process on production lines, and expanding market opportunities.

1.4 Impact

As previously explained, counterfeiting is an increasing problem for pharmaceutical companies. There is enormous loss of income world-wide for these companies, as well as serious health and safety risks to consumers and patients. The primary package (syringe, vial, etc.) is of "Class 1" glass, and present techniques to mark it are not appropriate to fight against this counterfeiting issue. Inkjet techniques are easily erasable; RFID tags can be erased or altered; classic laser techniques (Excimer, CO2 or YAG) induce microcracks on the surface or inside the material. The only technology available on the market to fulfill these quality requirements is the Naginels technology. This technology has been recognized as a "best practice for anti-counterfeiting issues". Unfortunately, the present process time (120 pieces/min) is not appropriate to the production speed of the pharmaceutical industry (600 pieces/min).

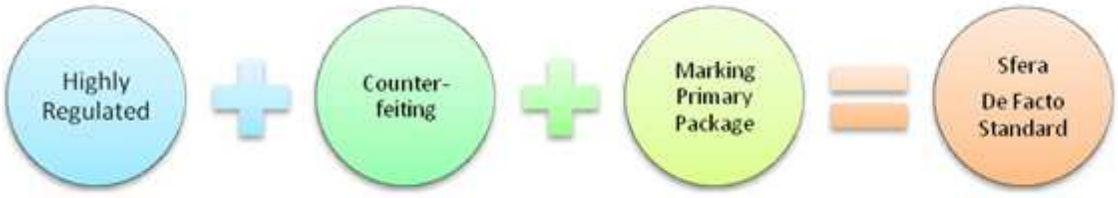
Another problem in the pharmaceutical industry concerns mix-up of products during the production process. High-speed lines must be able to redirect marked containers so they can be filled with appropriate product. Incorrect filling can result in health and safety issues for consumers and patients, if inappropriate products are used.

Contamination of containers is an additional issue. Any alteration to filled containers would require product to be further tested for approval. There is a risk of contamination from certain marking systems.

Following the SFERA project, we have overcome all technical barriers, have made the necessary technological breakthroughs, and have developed a specific system enabling the required cycle time (600 pieces/min). This innovative and quick process will allow monitoring of the supply chain, and identifying and significantly reducing counterfeiters, illegal diverters, and re-packagers.

The market exists and is awaiting our solution as shown by the short-series tests made for the major actors in the field during the two years of the project.

The SFERA Consortium is now in a position to create a "De Facto Standard" for the pharmaceutical market (syringes and vials):



It is proven that by better tracking and tracing during the production process, the delivery of quality Medical Products to consumers is improved. Also, tracking and tracing will help curtail counterfeiting and grey market issues. The fight against counterfeiting is a just cause, not least because it helps stem the possible flow of money to terrorist and other such destructive organizations, but also because it reduces the risk of potentially harmful products reaching consumers and patients.

As the pharmaceutical industry is a global one, SFERA Technology is very likely to become the global standard quickly, and will help benefit consumers, as well as protect employment in legitimate companies.

1.5 Project information

1.5.1 Project Logo

1.5.2 Project Web site

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SFERA

The goal of the SFERA project is to deliver a complete innovative solution by developing a new Sub-surface, Fast internal Engraving and Reading system suitable for Anticounterfeiting applications needed by the pharmaceutical industry.

Counterfeiting is a major global problem, with important societal and economic consequences, including the expansion of organised crime, loss of jobs and tax revenues, as well as serious health and safety risks, for which the pharmaceutical sector is particularly vulnerable.

The SFERA project will benefit from an experienced, market oriented industrial consortium to make the necessary technology breakthroughs for the laser and for the beam system. The targeted very high rates will also imply innovations on process/control, mechanical handling and vision systems.

SEVENTH FRAMEWORK PROGRAMME

Grant agreement No: 222057

Project acronym: SFERA

Project full title: Sub-Surface Fast Internal Engraving and Reading System for Anticounterfeiting Applications

Funding scheme: Research for the benefit of specific groups
Research for SME

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