

## Manufacturing Inspection Systems for the Pharmaceutical Industry \_\_\_\_\_

INSPECTION AND LEAK DETECTION MACHINES





## All For Safer Medicines

Since the 1950's Brevetti CEA is dedicated to advancing global healthcare by providing cutting-edge inspection and leak detection solutions for pharmaceutical injectable products.

With a steadfast commitment to quality and innovation, Brevetti CEA empowers its partners to achieve regulatory compliance and to ensure the **integrity**, **efficacy**, and **safety of injectable medications**, fostering trust among patients and healthcare professionals worldwide.

Through continuous research and development, Brevetti CEA plays a pivotal role in elevating global healthcare standards by **pioneering innovative inspection solutions for pharmaceutical injectable products**, setting new standards of excellence in the industry.

## **Global Presence**

At the heart of Brevetti CEA operations is the headquarters located in Sovizzo, Vicenza (Italy), a hub of innovation and excellence. Brevetti CEA headquarters serves as the nerve center for research, development, and the production of state-of-the-art inspection systems.



Complementing Brevetti CEA headquarters is a branch office located in New Jersey, in the United States, to provide efficient and direct support to the North American market.

Beyond Brevetti CEA physical locations, the global reach is further amplified through a robust sales network comprising 35 agents positioned worldwide.

These agents are not merely representatives but integral members of the organization, sharing Brevetti CEA commitment to excellence and ensuring that its cutting-edge inspection systems reach every corner of the globe.

As it continues to expand, Brevetti CEA remains dedicated to fostering collaborative relationships, driving innovation, and maintaining the highest standards of quality across its global operations.

## Pioneering Sustainable Manufacturing, Powering a Sustainable World

As a machine manufacturer, we recognize our essential duty in shaping the future of sustainability. Our commitment goes beyond producing cutting-edge technology; it extends to integrating environmentally conscious practices into every aspect of our operations.

Sustainability in manufacturing is a mission to minimize our ecological footprint while maximizing the positive impact on society. From energy-efficient production processes to responsible sourcing of materials, we strive to strike a delicate balance between innovation and environmental stewardship.

Beyond environmental aspects, we also embrace social responsibility, valuing the wellbeing of our employees and the communities we operate in.

We believe that by fostering a culture of inclusivity, safety, and employee empowerment, we can collectively work towards a better future.

#### OUR KEY VALUES:



## **Our Approach to Visual Inspection**

Brevetti Cea has been a pioneering force in the world of semi-automatic and automatic inspection solutions since the 1950s, revolutionizing the pharmaceutical industry's approach to quality assurance, consistently delivering cutting-edge inspection systems designed to meet the exacting standards of this industry.

Thanks to the fusion of cutting-edge vision innovations and a proprietary software, we offer high levels of accuracy and performance that are unique in the world.



Discover our Suite of innovative **Technologies Redefining** Inspection Excellence:

**Brevetti Al Studio** 

**Brevetti Intelligent Vision Framework** 

#### **Brevetti Technologies**

plunger (syringe with silk-screen print)

bubbles and detection of dark particle

## Brevetti Al Studio Supercharge Visual Inspection with Al



Brevetti CEA HMI software is "Deep-Learning ready" which means it is ready to host AI inspection networks as well as traditional computer vision algorithms or a combination of them.

#### A FULLY INTEGRATED DEEP LEARNING SOLUTION

Brevetti CEA integrates Al technologies in its vision software. The benefits of applying these new techniques involve detection performances, adaptive and intelligent methodology for developing new algorithms, better detection and classification of anomalies in images and, last but not least, an increased interaction between humans and machines.

In order to enable the usage of data-driven Deep-Learning and Machine-Learning algorithms to all Customers, Brevetti CEA developed an innovative and unique Al ecosystem of software components:

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The platform allows to manage a huge variety of data by the creation of datasets and by the addition of metadata such as labeling on images.

Brevetti Al Platform

A web-based workspace where data can be hosted, organized, labelled and fully traced in the cloud.

The platform complies with CFR 21 Part 11 and GMP Annex 11.

#### Brevetti Al Studio

A desktop application that can be used for training, evaluation and improvements of Al models, backend by Brevetti Al Platform or fully local according to customer requirements.

## Intelligent Vision Framework

The heart of Brevetti cea is fully expressed in the new working framework "Brevetti Intelligent Vision": an optimized integrated vision platform of consolidated and new technologies that enhances performance to a complete new level.

Optical Aligment

Advanced mechanical design guarantees precise **optical alignment** between cameras, lights and containers for superior detection performance. Fast container rotation is performed by controlled servo motors and can be independently adjusted according to each specific product.

Artificial Vision

Assisted machine learning tools for **deeper understanding** of the defects nature are applied in several Brevetti CEA inspections. Accurate parametrization has been highly simplified by introducing machine learning tools in the inspection software.

High Frame Rate

Multiple Inspection

High-resolution cameras acquire up to 100 images on each particle inspection unit. The high number of **frames is the key to ensuring accurate detection** and low risk of false rejects.

Particles detection based on image differentiation, thresholding and blob classification through physical features is now used in **combination with Brevetti CEA Particle Trajectory Tracking** based on background subtraction, blob extraction and motion prediction to reach higher efficiency and reduce false rejection.

The Brevetti HMI grants **real time live view of the inspection process**, a user-friendly guided parameterization tool as well as the innovative capability of storing images of rejected containers to allow process and quality investigation.



| Technologies   | Brevetti CEA cutting-edge technologies have been<br>meticulously integrated to successfully overcome<br>the challenges typically encountered in automatic<br>inspection processes.  |
|----------------|---|
| Simple Plus    | Designed to <b>simplify the often complex and time-consuming</b><br><b>process</b> of recipe parameterization, this tool represents the<br>future of intuitive and user-friendly recipe management.   |
| Meniscus Plus  | The meniscus, often a complex zone to scrutinize, is now easily<br>and comprehensively <b>inspected thanks to a dynamic</b><br><b>segmentation and tailored vision software features</b> .  |
| BubblePlus     | With Brevetti CEA revolutionary Bubble Plus, this complex task is executed with unprecedented precision. <b>Say goodbye to false rejects</b> and hello to a new era of precision!   |
| Roi Plus       | This tool empowers the operator to easily and <b>quickly draw</b><br><b>and define directly on the HMI the specific region to be</b><br><b>inspected</b> . Multiple shapes to draw the ROI are now available<br>and a complete fusion between AI and computer vision can<br>be applied! |
| Digi Twin Plus | With Brevetti CEA Digi Twin Plus, <b>operators can experiment</b> ,<br><b>fine-tune</b> , <b>and improve the process</b> in a controlled environment,<br>making adjustments and discovering new insights without<br>impacting your production line.                                     |

## Advanced Automatic Leak Detection Solutions for Compliant Container Closure Integrity (CCI) Testing

Brevetti CEA offers integrated and stand-alone leak testing solutions for liquid and freeze-dried pharmaceutical products based on different non-invasive, non-destructive testing methods that meet and exceed the evolving requirements outlined in the new EU GMP Annex 1.

| Non-Destructive Testing: | minimizing product loss and reducing costs associated with other traditional leak testing methods.            |
|--------------------------|---|
| High Precision:          | ensuring that even the most minute pinholes in container closure integrity are identified and addressed.      |
| Real-Time Monitoring:    | enabling continuous inspection and rapid detection of any potential leaks.                                    |
| Compliance Assurance:    | fully compliant with the latest regulatory standards, including but not limited to the updated EU GMP Annex 1 |

## High Voltage Leak Detection in Liquid (HV):

Pinhole, crack and pierced needle shield inspection can be detected by the HV principle developed by Brevetti CEA and based on the measurement of electrical conductivity of sealed containers using a high voltage electric field. LD module is the synthesis of more than thirty years of Brevetti CEA expertise in the inspection and leak detection world. Available as stand-alone machine, it can also be used in combination with our inspection machines, becoming the most compact and performing "Inspection Lines" for liquid filled ampoules, vials, syringes, cartridges, BFS and IV-bags available on the market

## Head Space Gas Analyzer in Freeze-dried (HGA):

Based on TDLAS spectroscopic technology, the laser is modulated in frequency to assure an accurate, stable and reliable measurement. Light absorption is proportional to oxygen concentration in the optical path. The system can discern oxygen-free (good) containers from the ones contaminated by oxygen due to leakage or process fault. The installation of HGA leak detection unit into an automatic inspection machine integrates the classic detection capabilities of visual inspection and it represents the state-of-the-art in terms of leak detection in products filled under low oxygen concentration or modified atmospheres (nitrogen).



#### Machines

## Inspection Machines for parenteral products



Brevetti CEA offers a comprehensive range of automatic inspection and leak detection machines for any type of injectable pharmaceutical products contained in syringes, vials, cartridges, ampoules, bottles, IV-bags and BFS.

Given the complexity and sensitivity of most of the pharmaceutical products, all Brevetti CEA systems grant smooth mechanical handling throughout the process. The integration of sophisticated no-contact handling solutions permits a fully automatic cycle, including de-nesting and re-nesting activities on both glass and plastic containers.

## Unlock Excellence.

Your **specific needs may require tailored solutions**. Our team of specialists is available to study and develop customized machines that can address the most complex technical requirements.

## Machines Portfolio

| Brevetti A50                  | AUTOMATIC   |
|-------------------------------|---|
| PRODUCT TO BE INSPECTED: CONT | TAINER TYPE: SPEED PER HOUR / CONTAINER SIZE:                     |
|                               | s, Ampoules, 9000 up to ø 52.00mm<br>ridges 18000 up to ø 52.00mm |
|                               |   |
| Brevetti A50-450              | AUTOMATIC   |
| PRODUCT TO BE INSPECTED: CONT | TAINER TYPE: SPEED PER HOUR / CONTAINER SIZE:                     |
|                               | s, Ampoules, 27000 up to ø 32.00mm<br>rridges                     |
|                               |   |
| Brevetti A35                  | AUTOMATIC   |
| PRODUCT TO BE INSPECTED: CONT | TAINER TYPE: SPEED PER HOUR / CONTAINER SIZE:                     |
|                               | s, Ampoules, 18000 up to ø 32.00mm<br>ridges                      |
|                               |   |



#### Brevetti A30

PRODUCT TO BE INSPECTED:

Water-like, Freeze-dried, Suspensions, Oily CONTAINER TYPE: Vials, Ampoules, Cartridges SPEED PER HOUR / CONTAINER SIZE:

AUTOMATIC

12000 up to ø 36.00mm



#### Brevetti K32S

PRODUCT TO BE INSPECTED:

Water-like, Freeze-dried, Suspensions, Oily

#### CONTAINER TYPE:

Vials, Ampoules, Cartridges

#### SPEED PER HOUR / CONTAINER SIZE:

AUTOMATIC

AUTOMATIC

AUTOMATIC

24000 up to ø 32.00mm 36000 up to ø 32.00mm



#### Brevetti K15 DR

PRODUCT TO BE INSPECTED: Water-like Suspensions CONTAINER TYPE:

Syringes

SPEED PER HOUR / CONTAINER SIZE:

24000 up to ø 14.45mm 36000 up to ø 10.85mm

| AREA UNIT     |
|---------------|
| <br>2 • 2 • 2 |

#### Brevetti K15

PRODUCT TO BE INSPECTED: Water-like Suspensions CONTAINER TYPE:

Syringes

SPEED PER HOUR / CONTAINER SIZE:

12000 up to ø 14.45mm 24000 up to ø 14.45mm 36000 up to ø 10.85mm

AUTOMATIC



#### Brevetti IVB-40

PRODUCT TO BE INSPECTED: Water-like

container type: IV-Bags SPEED PER HOUR / CONTAINER SIZE:

2400 from 50ml to 1000 ml



# Brevetti BH-S600 AUTOMATIC PRODUCT TO BE INSPECTED: CONTAINER TYPE: SPEED PER HOUR / CONTAINER SIZE: Water-like, Vials, Ampoules 36000 up to ø 32.00mm Suspensions, Oily Vials of the second sec



#### Brevetti BL-S300

product to be inspected: Water-like

CONTAINER TYPE:

Vials, LV

SPEED PER HOUR / CONTAINER SIZE:

AUTOMATIC

18000 up to ø 49.00mm 16000 up to ø 66.00mm 14000 up to ø 78.00mm 12000 up to ø 95.00mm



#### **Brevetti LDM**

PRODUCT TO BE INSPECTED:

Water-like Suspensions

#### CONTAINER TYPE:

Vials, Ampoules, Cartridges, Syringes, BFS, IV-Bags SPEED PER HOUR / CONTAINER SIZE:

AUTOMATIC

24000 up to ø 32.00mm



#### **Brevetti A1**

PRODUCT TO BE INSPECTED: Water-like, Freeze-dried Suspensions, Oily CONTAINER TYPE:

Vials, Ampoules, Cartridges, Syringes, BFS AUTOMATIC - SEMIAUTOMATIC

SPEED PER HOUR / CONTAINER SIZE:

3000 up to ø 95.00mm



#### Brevetti BSA02

PRODUCT TO BE INSPECTED: Water-like, Freeze-dried Suspensions, Oily CONTAINER TYPE:

Vials, Ampoules, Cartridges, Syringes SEMIAUTOMATIC

SPEED PER HOUR / CONTAINER SIZE:

3000 up to ø 52.00mm



## Discover our all services

At Brevetti CEA, we understand that the success of your operations hinges on the seamless functioning of our equipment. That's why we offer a comprehensive package of after-sales services designed to keep your production lines running smoothly and efficiently.



#### After - Sales services:

Our Global Service Centre Network is well-equipped to support your daily machine maintenance and tuning. Each local service centre is tailored to meet market demands, with full assistance from Brevetti C.E.A.'s Customer Support Services. We offer a comprehensive package of after-sales services, including customized solutions for specific operational needs and processes to maximize your investment.

#### Spare parts:

Thousands of Brevetti C.E.A. inspection machines are in operation globally, making us the preferred partner for successful investments. Using original parts is essential for machine reliability and availability. Our dedicated Spare Parts Team is ready to provide a customized Production Security Parts package to optimize stock, extend machine life, lower maintenance costs, and enhance efficiency and productivity.

#### Preventive maintenance:

To ensure proper machine maintenance, we offer a customized Preventive Maintenance package, minimizing breakdowns, reducing repair costs, and boosting profitability. When combined with our Production Security Parts package, Preventive Maintenance also provides an opportunity to share Brevetti C.E.A.'s expertise with your staff.

#### Predictive maintenance:

Our Integrated Predictive Maintenance (IPM) solutions detect and address potential machine failures before they happen, minimizing downtime. Brevetti C.E.A.'s IPM solutions enhance machine reliability, reduce maintenance expenses, and improve equipment availability. **We offer two solutions**:

- Offline IPM: This involves accelerometer sensors integrated into the machine for periodic monitoring of critical components.
- Online IPM: Our embedded 24/7 online condition monitoring system provides continuous automatic supervision of critical components directly on the machine's HMI.

#### **Remote solutions:**

Our Remote Service provides swift assistance for maintenance and breakdowns. Our Help Desk is ready for immediate support. Through Remote Assistance, our specialists can interact directly with the machine's HMI, allowing them to monitor, diagnose issues, troubleshoot, adjust parameters, and more in real-time. This minimizes downtime, reduces risk, and lowers costs. We also offer a "Remote Parameterization and Validation module" for product adjustments, production optimization, and false reject analysis, eliminating the need for on-site technical intervention.

#### **Embedded engineer:**

A Brevetti C.E.A. Embedded Engineer offers on-site support for various tasks, including preventive maintenance, troubleshooting, condition monitoring, performance analysis, and more. Here are the key benefits:

- Obtain skilled resources to quickly and efficiently complete projects;
- Reduce response time to equipment malfunctions and unplanned downtime;
- · Perform preventive maintenance as scheduled;
- Reduce risk of performance problems and premature equipment failures;
- Improve machine operator skills and internal troubleshooting capabilities;
- Supplement operations / maintenance staff during peak workloads;
- Fully protect Customer investment.

#### Training:

Skilled staff grants high productivity results, cost reduction and process optimization. Brevetti C.E.A. qualified experts are available to share and transfer their know-how to Customer personnel. Our training programs are structured and developed according to specific needs and are aimed to transmit the required knowledge and skills to all participants.



#### **BREVETTI CEA S.P.A.**

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