Visual inspection is a mandatory practice for injectable manufacturers to guarantee both quality and patient safety. The finished products must be inspected to identify and reject visible foreign matter contaminated parenteral containers and units displaying defects that could potentially affect product quality.

According to EU GMP: Annex 1 – Manufacture of Sterile Medicinal Products #124 – Filled containers of parenteral products should be inspected individually for extraneous contamination or other defects (...)

WHO Annex 6 – GMP for sterile pharmaceutical products #13.8 – Filled containers of parenteral products should be inspected individually for extraneous contamination or other defects (...)

USP 37: <1> Injections – Foreign and Particulate Matter – (...) Each final container of all parenteral preparations shall be inspected to the extent possible for the presence of observable foreign and particulate matter (...). Every container that shows evidence of visible particulates shall be rejected.

Bonfiglioli Engineering’s in-line and off-line automated visual inspection machines are computer based automated systems that, taking images of packages, determine if the container is fit to comply with given standards.

A suitable collection of images of the Package is acquired using high resolution
video cameras.

Defects on the package are identified and/or measured by dedicated image processing algorithms and the package is classified as conforming or non-conforming accordingly. Non-conforming packages are automatically rejected.

Visual inspection systems can be integrated with other testing methods into combined technology machines.
Custom inspection can be provided too with each specific product peculiarity. Detection of wrong fill level and liquid color for example:

fill level is evaluated by a dedicated ROI; meniscus position is calculated and compared to preset threshold ± tolerance while the color of a liquid product within the package is identified through a dedicated ROI and by using the RGB color model.

Bonfiglioli Engineering provides its systems with dedicated cameras for the detection of rubber stopper absence, defective crimp, dents, flip off damages and wrong color, cap scratches and deformations as well as inclusions, burnings etc. in the top portion of the inspected containers.

On request, employing X-Ray based technology, functional defects such as bent needle, cut-off needle tip, defective luer-lock, imperfection in the needle socket too can be detected when inspecting pre-filled syringes.
Cosmetic defects in parenteral containers can vary according to materials.

Bonfiglioli Engineering’s systems can detect scratches, spots, burnings, cracks, deformations, black spots or marking defects as well as determining lack of package material, packages overlapping, outdistancing or wrong orientation on the conveyor, code marking, mold number, batch ID expiry date etc...
Detecting foreign particulate matters in parenteral containers is necessary to assure the content safety for the final user. Even when the packaging process is well monitored, foreign matters can still contaminate the product from multiple origins:

- Extrinsic (from outside the process) as environmental contaminants: insect parts, hair, fibers, paint, rust etc.
- Intrinsic (from within the process) as processing equipment, primary package qualified product contact materials like stainless steel, aluminum, glass, rubber, silicone oil...
- Inherent (part of the formulation) like protein agglomerates.

Bonfiglioli Engineering systems use double lightning technology to detect such defects within the package:

Polarized visible light and infra-red non polarized (730-850nm)

In inspecting liquid content packages to detect particles and fibers (reflecting and non-reflecting), packages are provided with a fast spin along its vertical axis and then stopped abruptly in order to create a vortex in the content. During the passage in front of the cameras with the package still and the liquid in rotary motion, a set of images is acquired. Strobe light switches on and remains in this condition during the images acquisition process.

Inspecting powder content packages, the container is set to spin once in front of the cameras to acquire a 360 degrees panoramic of the surface. Dedicated cameras on top and bottom complete the inspection.
OVERVIEW

- The machine is designed for non-destructive and non-intrusive Automatic Visual Inspection (AVI) of containers with pharmaceutical products.
- The machine is suitable for 100% in-line and off-line inspection at high production speed.
- AVI is performed using high resolution cameras coupled with illuminators automatically positioned so to magnify regions of interest and designed according to defect type.
- The measurement system is a computer-based automated system that, taking images of packages, visually inspect them to detect visual defects through image acquisition, processing, and decision making.
- Defects that can be detected using AVI include but are not limited to: presence of foreign contaminants (particles or fibers) inside the product (liquid or solid), cosmetic defects present on the container body and cap, product fill level, color, and product out of specifications.
- Containers and package systems that can be non-destructively inspected include all empty or filled (powder/lyo, transparent/opaque liquid with different viscosity and density) containers for which the defect can be visually detected from outside.
- The machine is designed and manufactured for installation in clean areas for less critical phases of sterile product fabrication (Class C and D).