

# Quality Assurance for Research and Development

**ZEISS Medical Industry Solutions**



Seeing beyond



## **From R&D to quality assurance of series production** in medical device manufacturing

Overcome the hurdles of research, development, and QA lab environments within this regulated industry. Our tailored hardware and software solutions fulfill industry standards and work as a coherent system, granting manufacturers the certainty they need to achieve the productivity they desire.

[zeiss.com/metrology/medical](https://zeiss.com/metrology/medical)

# ZEISS Medical Industry Solutions: Overcome the hurdles of a regulated industry

To fulfill the regulatory demands of medical technology authorities, manufacturers must go beyond the usual requirements in quality assurance. Not only must industry-specific workflows be correctly set up, manufacturers must be able to document and validate that these workflows are consistently followed. Quality assurance hardware and software must work hand in hand to provide appropriate functionality while linking seamlessly to the subsequent steps of series production.

The processes and priorities involved in research and development work are often different to those in production settings. Precision, speed, and innovative non-destructive testing (NDT) are crucial for mastering QA lab applications and powering progress in the medical field. Connected workflows and correlative microscopy are now taking things to a whole new level.

Manufacturers must implement appropriate quality assurance processes to handle the detailed steps involved in medical device research and development – as well as in QA lab environments. This will enable them to generate safe and effective solutions while demonstrating their ongoing compliance with medical regulations.





# R&D in your quality lab

## For all medical device applications

Exacting standards are essential to the medical industry. In addition, R&D tasks and QA lab environments present major challenges within a wide range of applications. Since medical parts are critical to patients' quality of life, superlative quality is a must.

R&D in the medical field aims to improve patient outcome. From CMMs to optical systems and from X-ray CT systems to microscopes, ZEISS has got you covered. See below for an at-a-glance guide to how our products serve your R&D needs. You can learn more about these key applications on the following pages.



1 ZEISS O-INSPECT    2 ZEISS PRISMO    3 ZEISS METROTOM    4 ZEISS Versa    5 ZEISS Sigma    6 ZEISS LSM 900    7 ZEISS Axio Imager    8 ZEISS Smartzoom 5    9 ZEISS ATOS 5    10 ZEISS ARAMIS

		1	2	3	4	5	6	7	8	9	10
Material composition analysis	<a href="#">page 07</a>				✓	✓		✓			
Int. defect/structural inspection	<a href="#">page 07</a>			✓	✓	✓	✓	✓	✓		
Surface analysis	<a href="#">page 08</a>	✓	✓	✓	✓	✓	✓	✓		✓	
Coating analysis	<a href="#">page 08</a>			✓	✓	✓	✓	✓			
Technical cleanliness analysis	<a href="#">page 09</a>					✓	✓	✓			
NDT and assembly control	<a href="#">page 09</a>	✓	✓	✓	✓	✓				✓	
Dimensional analysis (ext./int.)	<a href="#">page 10</a>	✓	✓	✓	✓					✓	
Mechanical property analysis	<a href="#">page 11</a>				✓						✓

Where multiple products serve the same field of application, the resolution level and specific requirements will dictate the ideal choice from the product portfolio.





# Quality solutions for medical device R&D applications

## Material composition analysis

Analysis of structure, topography, and chemical composition

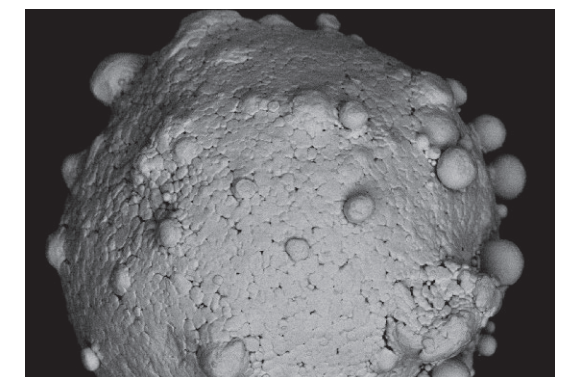
### Challenges:

- Characterization of bulk stock material or raw powder
- Crystallographic structure quantification of samples to meet international standards
- Identification of material chemical composition
- Material quality assessment: porosity, cracks, grain structure
- Identification of contaminants and non-metallic inclusions in materials

### Quality solutions:

#### Microscopy analysis

- Automated capture of large powder particle or raw material sample size via light microscopy: ZEISS Axio Imager with motorized stage
- Segmentation and auto-evaluation of porosity, crack, and inclusion images within predefined ZEISS ZEN core job template
- SEM analysis with ZEISS Sigma field emission scanning electron microscope
- Automated EDX measurements in ZEISS SmartPI software reveal chemical composition of material



### Added value



- Consistent material feedstock quality with early detection of fluctuations
- Avoid contaminants and large variation in elemental composition for part quality
- Assess material recycling/reuse strategy
- Best-in-class light microscopy image quality for cryptographic structure evaluation

## Internal defect and structural inspection

Structural integrity of the part

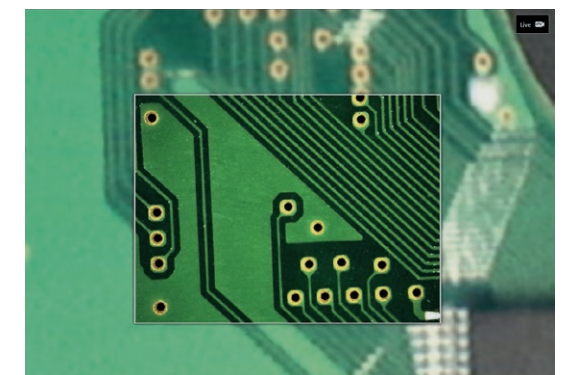
### Challenges:

- Eliminating defects (pores and cracks) above a critical size to meet static or fatigue performance requirements
- Material inclusions can increase localized part brittleness
- Process stability monitoring for consistent part quality

### Quality solutions:

#### CT, X-ray, light microscopy (LM), scanning electron microscopy (SEM), laser scanning microscopy (LSM)

- ZEISS scatterControl for CT to reduce scattering artifacts of high-density materials such as CoCr and stainless steel
- ZEISS METROTOM/ZEISS Versa XRM: non-destructive volumetric part scans to identify internal defects/cracks
- Segmentation of pores and foreign metal inclusions in materials using ZEISS INSPECT X-Ray
- Guided inspection: higher-resolution scans of critical regions
- AI-based defect detection with ZADD Segmentation app
- ZEISS Axio Imager, ZEISS Smartzoom 5, ZEISS LSM 900: light microscopes and laser scanning microscope for visual inspection to identify surface failures
- LM for fracture surface imaging to identify failure mode and potential initiation point
- ZEISS EVO, ZEISS Sigma: SEM for high-resolution imaging of fracture features and failure propagation
- Elemental analysis to confirm correct bulk material composition, also performed using SEMs with EDS to find defect root cause



### Added value



- Identify quality problems via NDT of circuit boards using XRM or optical inspection
- Compute volumetric density of parts
- Determine pore location, size, and shape to estimate mechanical performance impact
- Calculate number of inclusions to monitor process cleanliness
- Metrology measurements (strut thickness, 3D porosity) on trabecular structures
- Build qualification and process parameter optimization based on part geometry for medical additive manufacturing (AM)



## Surface analysis

Non-contact handling of surfaces

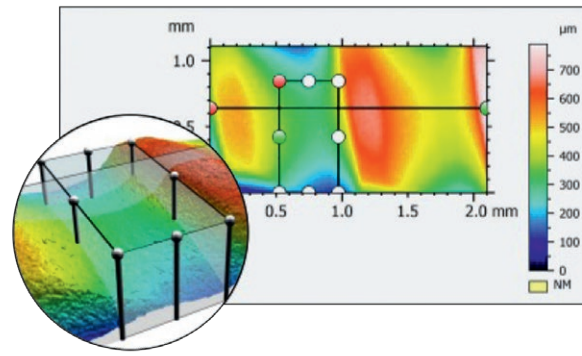
### Challenges:

- Characterizing structural coatings on complex hidden inner surfaces (porous/trabecular structures): non-contact inspection
- Characterizing active surface coating (hydroxyapatite)
- Identifying thickness/structure of protective surface coatings
- Evaluating bonding of protective coating and substrate
- Evaluating surface treatments
- Understanding surface roughness

### Quality solutions:

#### X-ray CT, XRM (X-Ray Microscopes), and CMMs

- ZEISS Axio Imager/Sigma/LSM 900: ext. surface requirements
- ZEISS Versa XRM/ZEISS METROTOM: complex hidden int. surfaces
- Section of bulk material can be prepared for LM/EM imaging to visualize coatings for further imaging and analysis acc. to medical standards such as F1854
- ZEISS ZEN core software modules: evaluate structural coatings
- Also for layer thickness measurement of active/protective coating
- High-resolution SEM: visualize surface structure, substrate bonding
- Confocal microscopes to evaluate surface roughness
- Form, size, position: ZEISS DotScan on ZEISS PRISMO/O-INSPECT
- Tactile roughness measurement with ZEISS ROTOS and ZEISS PRISMO



#### Added value ✓

- Full characterization of surface coatings, layers, or treatments using LM/SEM
- Non-contact inspection eliminates part marking used in traditional methods
- Correlative microscopy used to aid LM to SEM to XRM investigations
- Image acquisition/analysis software makes ZEISS a single-source provider of cross-platform microscopy solutions
- Improved implant quality via reduced fatigue of working surfaces

## Coating analysis

Robust quality monitoring with AI support

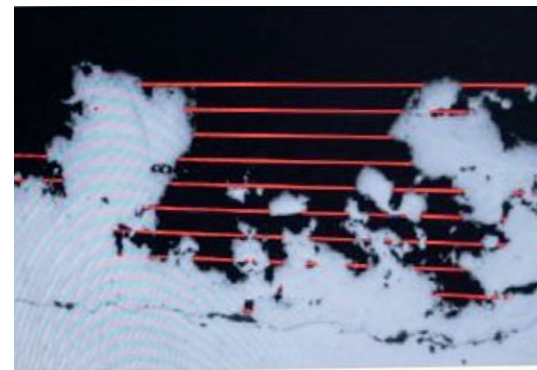
### Challenges:

- Complex surface coatings: time-consuming and hard to evaluate
- Need highest accuracy to monitor quality of surface coated structures in line with international standards (DIN ISO, ASTM)
- Robust coating quality analysis supports integrity of medical device during its working life cycle
- Complex structures require advanced AI-based software analysis to ensure part quality and productivity

### Quality solutions:

#### XRM and combined microscopy

- ZEISS Axio Imager, ZEISS Sigma, ZEISS Smartzoom 5, and ZEISS LSM 900 microscopy
- ZEISS Versa 3D X-ray microscope (XRM): non-destructive imaging at submicron resolution
- Automated segmentation of multi-dimensional images including 3D datasets with ZEISS ZEN Intellesis
- ZEISS ZEN core software suite for multi-modal microscopy
- ZEISS ZEN core AI platform with ZEISS arivis Cloud for AI image analysis based on deep learning



#### Added value ✓

- Robust analysis methods deliver repeatable and reproducible results
- Latest AI technology can boost productivity by an order of magnitude
- Result report meets international standards
- Automatic/interactive evaluation of complex layer systems

## Technical cleanliness analysis

Adaptable and correlative workflows

### Challenges:

- Particle contamination detection that meets strict standards e.g. VDI 2083 page 21
- High-quality particle itemization and classification
- Combining LM and SEM data in correlative solution for more productivity and simpler technical cleanliness process
- Minimizing maintenance costs via swift measurement and analysis of critical particles

### Quality solutions:

#### TCA and combined microscopy

- ZEISS Technical Cleanliness Analysis (TCA): adaptable workflow with analysis, reporting, and archiving in just a few clicks
- ZEISS ZEN core TCA module for reliable and reproducible results with high productivity
- Light and scanning electron microscopy data combined in a single process



#### Added value ✓

- TCA: one-scan root cause identification
- Early detection saves resources, cuts downtime, meets tough standards
- High-res bundles for correlative solutions, uniquely from single source
- LM plus SEM for up to 10x faster results
- Increase productivity with ZEISS Technical Cleanliness object classification

## Non-destructive testing/assembly control

Non-destructive fully assembled inspection

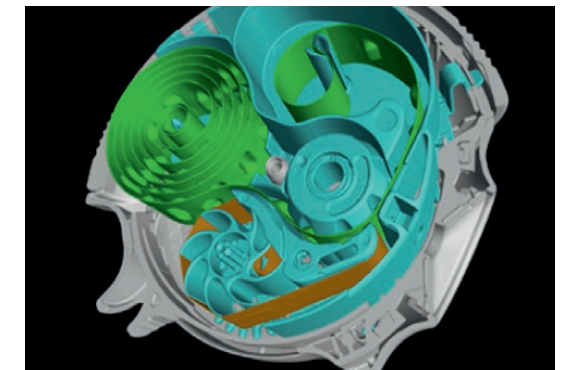
### Challenges:

- Drug delivery devices require a stringent quality assurance process for assembly control purposes
- Non-destructive testing (NDT) crucial to assess interaction of internal components while keeping medical device intact
- Medical device quality control depends on ability to assess complete assembly with active ingredient added

### Quality solutions:

#### XRM and X-ray CT

- ZEISS Versa 3D X-ray microscope: visualize and evaluate submicron internal structures incl. active ingredients
- ZEISS METROTOM X-ray CT systems for full characterization of internal structures and components
- Easy NDT and evaluation of complex devices with ZEISS INSPECT X-Ray
- Full device characterization enables evaluation of porosity, inclusions, geometry, and assembled functionality
- Advanced multi-material artifact reduction: better analysis of components with diverse materials (polymers, metals, ceramics)



#### Added value ✓

- Full NDT characterization: less uncertainty caused by part distortion during sampling
- Swift AI assessment of non-conforming areas plus clear full 3D visualization
- Handle all requirements of medical device assembly control in one easy step
- Inspection of fully assembled workpiece is vital for medical device manufacturing
- Easy root cause analysis of failed parts after fixation



## External dimensional analysis

Precision handling of surfaces and tolerances

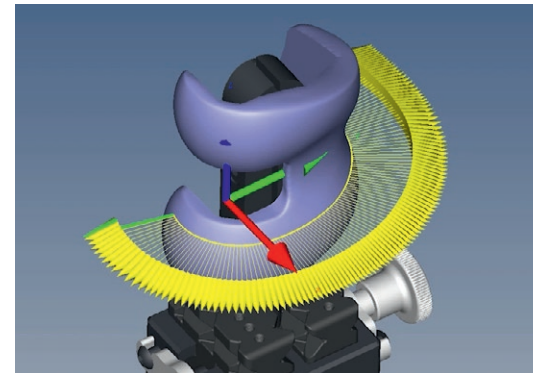
### Challenges:

- Measure/verify all geometrical product specifications (GPS)
- Quality control of complex 3D surface structures
- Wide variety of precise QA requirements in modern processes requiring full part digitization
- Non-contact measurement of precision mirror surfaces and non-touch flexible plastic components
- Meeting multi-load requirements to boost productivity
- Fixturing requirements due to complex 3D geometry

### Quality solutions:

#### Optical scanners and CMMs

- Micron-range active scanning with ZEISS PRISMO CMM
- ZEISS mass technology for CMMs: flexible multisensor systems
- Pinpoint critical parts of geometry prone to quality issues using ZEISS O-INSPECT multisensor CMM
- Easy scanning of fragile/flexible components with ATOS Q
- Manual and automatic ATOS systems auto-inspect part batches without being affected by complex geometries
- Simultaneous int./ext. feature measurement with ZEISS METROTOM



### Added value

- Fast, easy measuring with simple go/no-go
- Understand full 3D surface deformation for better process control and fewer rejects
- Model compensation meets print tolerances
- Software de-warp functionality for virtual compensation of warpage on flexible parts
- Full digital twin data acquisition via ATOS blue light optical inspection
- Reverse engineering with model compensation for component distortion correction in AM

## Internal dimensional analysis

Visualization, comparison, verification

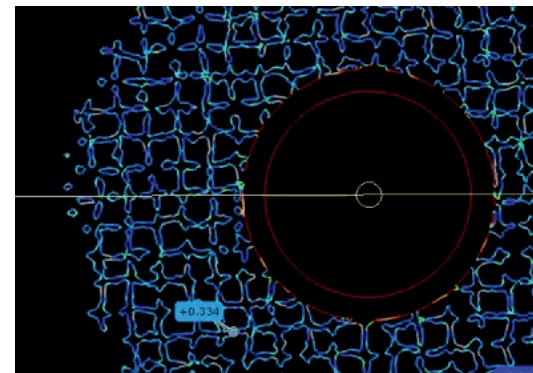
### Challenges:

- Quality control of structurally important internal features
- Non-destructive visualization of complex internal structures
- Full-field nominal/actual comparison of internal characteristics
- High-resolution imaging of internal defects

### Quality solutions:

#### X-ray CT and XRM

- ZEISS Versa 3D X-ray microscope (XRM): non-destructive imaging at submicron resolution
- ZEISS METROTOM: perform dimensional inspection and digitize complex parts including internal geometries
- Simultaneous measurement of interior and exterior features via ZEISS METROTOM



### Added value

- Verify critical internal dimensions that are key to validating medical device quality
- Accurately align actual data with nominal internal geometries
- Quick, precise dimensional assessment of complex internal features
- Sub-micron accuracy for R&D settings

## Mechanical property analysis

3D optical measurement

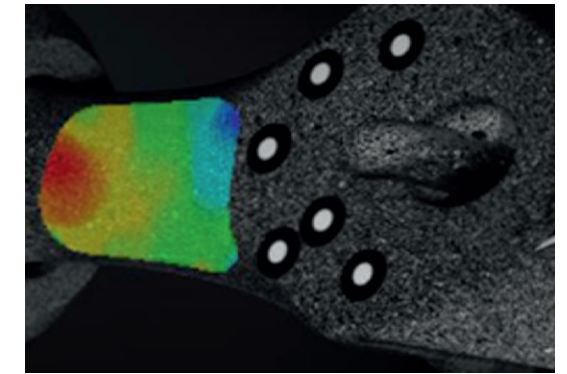
### Challenges:

- Hard to attach strain gages/displacement transducers to small medical devices: incomplete data, impaired accuracy, not suitable for delicate and soft biomaterials like tissue and tendons
- Difficult to interpret results generated with these technologies due to complex motion patterns within human body kinematics
- Improperly fixed implant may move, impairing test results

### Quality solutions:

#### ZEISS ARAMIS 3D measurement system

- Non-contact optical measurement: no biomechanical test article interference, no strain gage slip, no improper sensor fixtures
- Prepare optical measurement using high-contrast color patterns and ultra-light, super-small measurement markers
- Analyze article under test for motion and deformation
- Analyze test rig to see if experiment performs as intended
- Augmented visualization by aligning imported CT scans with 3D measurement data; track points that are not directly visible



### Added value

- Quick setup means test bench components can also be integrated into measurement
- Perfect for preparing delicate biomaterials and orthopedic implants even in small sizes
- Holistic measurement database suitable for intuitive visual interpretation
- Resolve issues affecting implant fixation





# Dynamic software workflows

## Get connected with ZEISS

### Process data and analytics

Get to the heart of your process

ZEISS software supports data collection, advanced analysis, and exchange across the entire process chain. Clear visual representation and correlation of results throughout all steps helps you develop your R&D strategies – while increasing your yield quickly and more efficiently.

#### ZEISS CONNECTED QUALITY

Data aggregation and exchange

With ZEISS CONNECTED QUALITY, you get the truth on your global metrology operations from a single source. This software powers agnostic, traceable, secure, and global quality processes, offers access to system health and utilization data, and contributes to centrally managed global quality operations.

In addition to providing basic analysis of results data, it enables efficient management and planning of inspections. Users can implement condition monitoring for their measuring systems with integrated alerts, all while enjoying raw data access to ZEISS measuring systems for new use cases. A truly global solution for easy worldwide collaboration.

#### ZEISS PiWeb

Data evaluation and statistics

ZEISS PiWeb enables the overarching evaluation of quality result and production data. Users can deploy statistical and advanced analysis in order to analyze quality and production data incorporating processes and results.

This software helps you make quick and informed decisions by visualizing complex data in an easily understandable format. Its numerous powerful functions allow you to control and improve your manufacturing and quality processes.

### Connected microscopy

Accelerate decision making

ZEISS ZEN core software suite bundles a wide variety of microscopy solutions for medical research and development. It comprises the most comprehensive portfolio of imaging, segmentation, analysis, and data connectivity tools.

#### Correlative workflow

The uniform user interface allows users to operate all microscopes in the same way, from stereo microscopes to fully automated high-end applications. With this powerful software suite, you can transfer specimens from one microscope system to another in a matter of minutes.

#### Data storage

ZEISS ZEN Data Storage supports data and workflow exchange between different systems, labs, and locations. It also enables server-based user management and centralized data handling. All images, templates, forms, and reports are accessible in a single hub.

#### Speed up with AI

Automate your workflows and image segmentation with the ZEISS ZEN AI Toolkit. Generate reproducible, precise, and operator-independent results.

#### Compliant traceability

ZEISS ZEN core GxP Toolkit uses seamlessly integrated microscopy hardware and software to power traceable workflows. Perfect for meeting the requirements of the highly regulated medical industry.



# ZEISS portfolio



Want to explore all hardware and software solutions across the entire ZEISS portfolio? Visit us at [zeiss.com/metrology](https://zeiss.com/metrology)

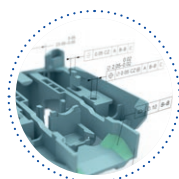
## Coordinate measurement solutions



ZEISS CMMs deliver stunning speed, accuracy, and flexibility, while ZEISS VMMs (vision measuring machines) offer outstanding point density for fast optical measurement results.

### ZEISS CALYPSO

ZEISS CALYPSO is your dimensional metrology software solution for CMMs.



### ZEISS Smart Services

ZEISS Smart Services boost safety, availability, and productivity.



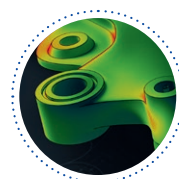
## Optical solutions



ZEISS manual and automatic scanning delivers fast high-resolution results for small to medium components. ZEISS optical solutions enable dynamic object measurement to test for deformation or movement.

### ZEISS INSPECT

ZEISS INSPECT Optical 3D software takes inspection and evaluation to a whole new level with features such as full-field data acquisition and trend analysis.



## CT and X-ray solutions



2D and 3D X-ray solutions from ZEISS are ideal for fast and non-destructive part evaluation. ZEISS industrial CT enables precise measurements and defect analyses via the data from a single X-ray scan.

### ZEISS INSPECT

ZEISS INSPECT X-Ray software performs in-depth visualization and analyses using the data generated with industrial CT.



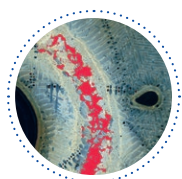
## Microscopy solutions



ZEISS offers precision solutions in light, digital, electron, and X-ray microscopy, from specific surface inspection to general material characterization.

### ZEISS ZEN core

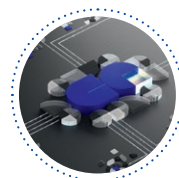
The powerful imaging and connectivity software ZEISS ZEN core enables traceable analysis and ensures compliance with regulatory demands.



## Supporting software

### Data exchange

The truth from a single source: ZEISS CONNECTED QUALITY enables agnostic, traceable, secure and global quality processes, offers access to system health and utilization data, and contributes to centrally managed global quality operations.



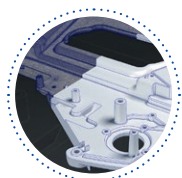
### Data management

ZEISS PiWeb scalable reporting and quality management software combines metrology results from different measuring technologies for efficient tracking of production quality. Its powerful features and intuitive templates handle huge amounts of data and provide immediate results.



### Reverse engineering

ZEISS REVERSE ENGINEERING surface reconstruction software promotes the automated, interactive, and highly precise creation of CAD models. The additional tool correction option helps improve CAD data quality.





# ZEISS Industrial Quality Solutions – Present in all regions

38

Sales & service organizations

11

Production sites

245

Salespartners worldwide

4,800

Employees

63

ZEISS Quality Excellence Centers

For research and development activities relating to medical parts, precision measurement and inspection must be ensured at sites around the world. Our global network of application engineers and service technicians provide quality assurance solutions to help you keep traceability and quality at a consistently high level.

Want to know which solution is perfect for you?  
**Get in contact with our global medical experts.**



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