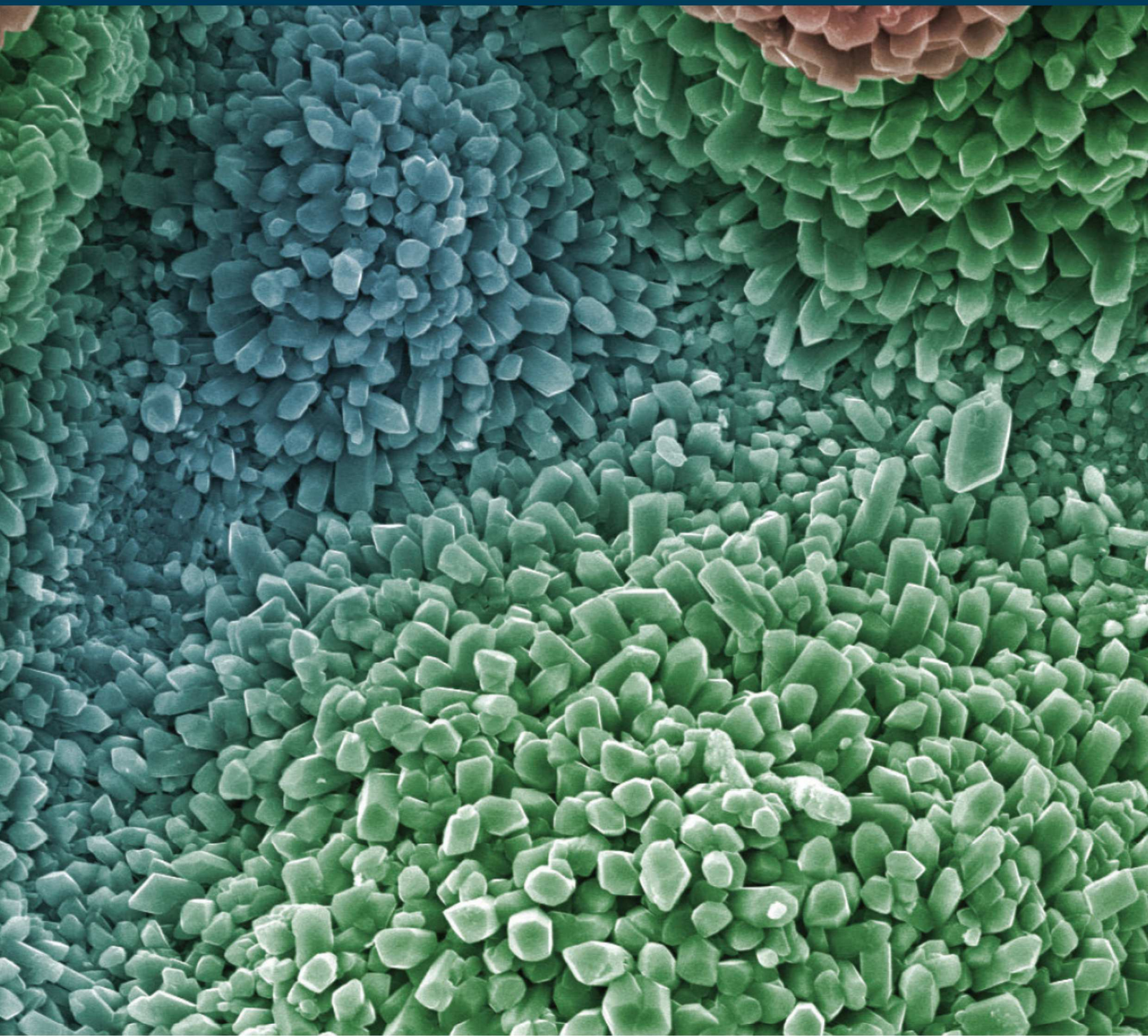


# Service catalogue





## SERVICE CATALOGUE OF THE RMS FOUNDATION

### INDEX

GENERAL INFORMATION	2
PHYSICAL AND CHEMICAL ANALYSES	2 – 4
MATERIALOGRAPHIC INVESTIGATIONS	5
MICROSCOPIC INVESTIGATIONS	5
PHYSICAL AND MECHANICAL TESTS	6 – 7
TRIBOLOGICAL INVESTIGATIONS	8
ADVICE / VALIDATION / LITERATURE (non-accredited services)	8



## GENERAL INFORMATION

The **general business conditions (GBC)** are the basis of our offers for testing and consulting services to all customers. The former are available under <http://www.rms-foundation.ch/GBC>.

All testing services are provided where possible according to a **standard** or according to internal measurement procedures. Modified tests and specific tests are also possible on request. Since 1995 an accreditation of our services in accordance with **ISO / IEC 17025** by the Swiss Accreditation Service (SAS) exists. Since August 2013, the accreditation covers all testing services (accreditation type C).

We bill the services on a time and material basis per hour or as unit price, partly sorted according to the number of units. Many tests require a preparation of the specimens. This will always be invoiced on a time and material basis, as it can strongly vary depending on the material and shape. This applies as well to the establishment of reports or to test certificates.

In the individual case, we recommend that you demand an **offer**. You will have to provide the specifics regarding the desired tests, the number, the type of specimens, and the desired reports / certificates (language). We will be happy to make you an offer for your specific requirements. In case of discrepancies, we will support you as well in the formulation of the basics for a test plan. Basically we distinguish three types of offers depending on the complexity of the assignment:

**Fixed price offer:** We gladly quote you a fixed price for common and clearly defined test assignments. We invoice the described performances precisely according to the offered price (plus the legal VAT). Should the customer require other or additional non-offered performances when placing the order or in course of rendering the service, we shall invoice the additional costs separately.

**Target price offer:** We offer you a target price for more complex assignments on the basis of an estimate of the expenditure for the described performances. We effectively record the performances during the order processing. Should the expenditure remain below the offered target price, we will only invoice the effective costs. An exceeding of the offered amount by up to 15% is possible without any advance information. We will invoice additional services separately.

**Offer with cap on costs:** In novel Investigations, we will indicate a cap on costs for the described performances or those defined in the progress meeting. This is advisable as more complex and new task assignments include a risk for the unforeseen. We record and invoice the services during order processing. We will inform you as customer of any possible exceeding of the cap on costs and discuss the further proceeding.

If desired, we will provide you with monthly interim bills in case of longer-lasting, extensive assignments. This will give you a precise cost control. In short assignments, we only issue one final invoice after completion of the assignment.

The relevant employees of the RMS will be happy to provide you with further information. The responsibilities and contact data are available on our Website [www.rms-foundation.ch](http://www.rms-foundation.ch).

## PHYSICAL AND CHEMICAL ANALYSES

### **X-ray photoelectron spectroscopy (XPS)**

The X-ray photoelectron spectroscopy (XPS) is used to determine qualitatively and quantitatively the chemical composition of the near-surface areas (top 5-10 nm) of metallic and non-metallic solids. It is mainly used for the non-destructive detection of all the established elements (with the exception of hydrogen) and for the determination of the existing oxidation states of an element.

Device: *Kratos Axis NOVA*

### **Determination of C, S, H, N, O and Ar content in metallic materials**

This analysis is based on the inert gas fusion (IGF) principle, which involves melting of the sample material in a graphite crucible at high temperatures. The principle is also commonly termed a melt extraction (ME) It is used to determine the carbon, sulfur, hydrogen, nitrogen, oxygen and argon content of metallic or non-metallic materials.

Device: *LECO CS 230 carbon and sulphur determination device*  
*Bruker G8 Galileo & Mass spectrometer ESD 100*

### **X-ray fluorescence analyses (XRF) of metallic and non-metallic materials**

The qualitative and quantitative energy dispersive and wavelength dispersive X-ray fluorescence analyses (XRF) serve to determine the composition of metallic and non-metallic materials (all elements from sodium to uranium).

Device: *X-ray fluorescence spectrometer BRUKER S8 Tiger (WD-XRF)*  
*Handheld X-ray fluorescence spectrometer BRUKER S1 Titan LE (ED-XRF)*

### **Energy dispersive microanalyses (EDX)**

In the qualitative and quantitative analysis of the surface of solid or powdery materials, the energy dispersive spectroscopy by X-rays (EDX) on the electron microscope is used to identify the elements from boron to uranium contained in the sample surface. The quantitative analyses allow determining the content of selected elements.

Device: Zeiss EVO MA25 with Oxford x-Max 50 Detector

### **Inorganic analyses using inductively coupled plasma and mass spectrometry (ICP-MS)**

ICP-MS is a very robust and sensitive analytical method for the detection of inorganic compounds. It has a wide dynamic range of up to 9 orders of magnitude, down to pg/L. The ICP-MS technology is applicable for virtually any inorganic analytical task including the detection of wear debris in metal working fluids, residual heavy metals in materials (e.g. RoHS regulation) and food products, or the composition of drinking water, blood or tissues. Chemical digestion methods are applied prior to analysis if the sample is a solid or enclosed in an organic matrix such as for body fluids or oils.

Device: Agilent 7700x ICP-MS

### **Infrared spectroscopy (FTIR)**

Infrared spectroscopy (Fourier transform infrared spectroscopy FTIR) for the identification of organic compounds, polymers, adhesives, greases, oils, etc. A fully automated FT-IR microscope with motorized ATR crystal (ATR = attenuated total reflection) is available for measurements on microscopic samples (solids, powders, liquids) in the measurement modes transmission, reflection and ATR.

Device: FT-IR microscope Bruker Lumos

### **UV-VIS spectroscopy**

The UV-VIS spectroscopy serves to determine the metal ions and the anions in metallic or non-metallic samples after the extraction in a solution. The ultraviolet (UV) and visible (VIS) light stimulates the characteristic electron migrations in the molecules, and causes the absorption strength to correlate with the concentration of the (coloured) material of the solution (absorption bands occur due to the electron stimulation in an appropriate wavelength).

Device: UV-VIS photometer PerkinElmer Lambda 10

### **Calorimetric analyses (DSC)**

This differential scanning calorimetry (DSC) is used to measure a specimen's enthalpy variations when heated, cooled or at a constant temperature. This method enables not only to measure the temperatures at which the variations in enthalpy occur, but also the heat reactions in a quantitative way. The measurements can be realised in different gas atmospheres using various heating or cooling rates.

Device: Mettler STAR system DSC1

### **Microcalorimetric measurements of solutions and solid materials (non-accredited service)**

The measurement of the heat emitted by a chemical and/or physical reaction permits to pinpoint the heat-flow data in the milliwatt range and on isothermal conditions continuously as a function of time. During the measurement, the specially constructed «Admix» injection ampoule enables to mix and inject the liquids on isothermal conditions in order to investigate, for instance, the first phases of a cement reaction.

Device: TAM Air 3115/3238 Calorimeter (isothermal) with «Admix» injection ampoule, Thermometric Inc.

### **Setting time and setting reaction temperature**

This test setup determines the setting time and the maximum reaction temperature of exothermic cement reactions according to ASTM F451-99a (reapproved 2007).

Devices: Center 309 Data Logger with Thermocontrol TKI20/50FIM.K thermo couples

### **Residual moisture content**

The residual moisture content is calculated from the weight loss after intense drying according to Ph. Eur. Monography 2.2.32. „Loss on drying“ 01/2008:20232.

Devices: Drying furnace Memmert Typ ULP 500 and UFP 500 / Precision scale Mettler Toledo AX205

### **Cohesion of pastes and cements**

In a specifically developed test setup we analyze the cohesion of pastes and cements in an aqueous environment. The result reveals how fast a paste dissolves or disintegrates in water. The setup can analyze paste volumes from 0.5 to 10 ml at room temperature.

Equipment: Precision Scale Mettler-Toledo PR5002

### **Corrosion measurements (electrochemical methods)**

These measurements are used to determine the local corrosion properties of real surfaces of metallic materials using the EC-pen. Pen tip: A = 1.5 mm<sup>2</sup>.

Devices: EC-pen with Jaissle potentiostat

### **Titrimetric analyses**

This analysis permits to calculate an unknown quantity of a dissolved substance after its reaction to an appropriate reagent solution, to measure the exact volume of reagent used, and to take into account the content of the effective substance. The addition of a reagent with a known chemical efficiency (titre) permits to quantitatively convert the substance to be determined from an exactly defined chemical initial state into an equally defined final state.

Device: Mettler Memo-titrator DL 40 GP

### **Determination of the pH value**

Serves to determine the acid and/or the base value (pH value between 0 and 14) of an aqueous solution.

Devices: Mettler DL40GP Memotitrator / Mettler DG111 glass electrode und Knick Portamess

### **Determination of the residues on ignition of polymers**

The incineration or calcination method is used to determine the residues on ignition or the ash of polymers as well as the textile-glass and mineral-filler content of fibreglass reinforced plastics.

### **Determination of viscosity**

Serves to determine the inherent viscosity and molecular weight of PE and polylactides.

Devices: Lauda Viscoboy 2 and Lauda Proline PV 15 viscometer

### **Density of solids and liquids**

Determination of the density following the principle of Archimedes (measurement of the lifting force). The density of a solid is determined using a liquid of known density. The sample is weighed in air and in the liquid separately. The density is calculated from the two measurements.

The density of a liquid is determined using a displacer of known volume. The displacer is weighed in air and in the unknown liquid separately. The density is calculated from the two measurements.

Devices: Precision scale Mettler Toledo XS205DU with density kit

### **Determination of the specific surface area of powders and porous solids**

In the BET method (Brunauer, Emmet and Teller) we use gas adsorption to determine the specific surface of solids. The nitrogen adsorption at a temperature of liquid nitrogen is used as standard method.

Device: Tristar Plus 3030, Micromeritics

### **Identification and quantification of ceramic degradation products**

This test determines the amount of dissolved material from ceramic products according to ISO 10993-14.

Devices: Climate chamber Feutron KPK 200 / Orbital shaker GFL Type 3017 / Agilent 7700x ICP MS

### **Phase purity of $\beta$ -tricalcium phosphate**

The phase purity of  $\beta$ -tricalcium phosphate bone graft substitute material is determined by X-ray diffraction (XRD). Data evaluation by state-of-the-art Rietveld refinement was adapted from ISO 13175-3 and ISO 13779-3 and is compliant with ASTM F1088.

Devices: Bruker D8 Advance diffractometer with CuK $\alpha$  radiation and a LynxEye XE energy dispersive linear detector / current release of the ICDD PDF-4+ structure database / BGMN and Profex Rietveld refinement software

### **Identification of crystalline main phases (non-accredited service)**

Crystalline main phases are identified in ceramic and metallic samples by comparing an X-ray diffraction pattern (XRD) with a crystal structure database. Depending on the complexity of the diffraction pattern, phases of less than ten weight percent can be identified.

Devices: Bruker D8 Advance diffractometer with CuK $\alpha$  radiation and a LynxEye XE energy dispersive linear detector / current release of the ICDD PDF-4+ structure database / Match! identification software

## MATERIALOGRAPHIC INVESTIGATIONS

### Sample preparation for materialographic investigations

The preparation of samples for the materialographic investigation includes working steps such as cutting, embedding, grinding, polishing, and etching.

Devices: *Embedding press Metkon ECOPRESS®200 / grinding and polishing devices Struers TegraPol-21 (+ Tegra Doser 5) and PRESI Meccatech 334*

### Determination of the grain size and the volume fraction in multiple-phase structures

Determination of the grain size number and the grain size of metallic and ceramic materials based on standard methods as well as the volume fraction in multiple-phase structures by point count with picture documentation.

Devices: *Light microscope Leica DMI5000 M with camera ProgRes C14plus and Imagic ImageAccess Premium*

### Determination of non-metallic inclusions in metals

Characterization and determination of the non-metallic inclusions of non-etched sections of metallic materials with documentation.

Devices: *Light microscope Leica DMI5000 M with camera ProgRes C14plus and Imagic ImageAccess Premium*

### Determination of precipitated phase contents

Estimation of the contents of precipitated phases such as delta ferrite, sigma phase and ferrite series using standard series with documentation.

Devices: *Light microscope Leica DMI5000 M with camera ProgRes C14plus and Imagic ImageAccess Premium*

### Intergranular corrosion test ASTM A262 practice A and E

The test is used to detect intergranular attack in austenitic stainless steels. The oxalic acid etch test practice A is used as a method to rapidly screen certain grades of stainless steel. Practice E (Strauss test) is conducted to determine the susceptibility of austenitic stainless steel to intergranular attack associated with the precipitation of chromium-rich carbides.

Devices: *Practice A: electro-polisher/etcher Buehler ElectroMet 4  
Practice E: glass apparatus with return cooler*

### Measurement of coating thickness

Measurement of the local thickness of metallic coatings and oxide layers by investigating the cross-sectional surface by means of a light microscope with documentation.

Devices: *Light microscope Leica DMI5000 M with camera ProgRes C14plus and Imagic ImageAccess Premium*

## MICROSCOPIC INVESTIGATIONS

### Scanning electron microscopy (SEM)

The scanning electron microscopy (SEM) is used to document the surfaces and fracture surfaces of organic and inorganic test bodies and component samples to determine the topography and the structure of the surface.

Device: *Zeiss EVO MA25 with a secondary and backscattered electron detector, Alicona MEX Software (3D images, roughness measurements)*

### Light-optical microscopy, stereomicroscopy, macroscopic documentation

Macro- and microscopical documentation of of all kinds of samples.

Devices: *Inverse light microscope Leica DMI5000 M  
Stereo microscope Leica M205A  
Canon EOS 450D*

## PHYSICAL AND MECHANICAL TESTS

### **Tensile, compression, and bend tests**

The static and quasistatic tensile, compression, and bend tests of metallic samples and polymers as well as components are used to determine the tensile strength, the yield point, the contraction, the elongation at rupture, the modulus of elasticity and/or the flexural strength and the graphic recording of the test parameters.

*Devices: Zwick tensile testing machines 1475 and Z250 and Zwicki-Line Z5.0 with Software testXpert II (force and displacement according to accuracy class 0.5 - 1.0 to DIN EN ISO 7500-1 or DIN EN ISO 9513 respectively)*

### **Torsional test**

The static and quasistatic torsional tests of metallic samples and polymers as well as of components are used to determine the torsional stiffness, the torsional strengths including the resulting twisting angles, and to measure the tightening/loosening moments with a graphic recording of the test parameters.

*Device: Torsion testing machine Zwick TL500 (Software testXpert II)*

### **Technological bend test (flexibility test)**

The technological bend test used as flexibility test serves to verify the plastic deformability of metallic samples with a rectangular, spherical or polygonal cross section and includes a visual or microscopic investigation for cracks.

*Devices: Zwick material testing machines 1475 and Z250 and bending device with two rotating supporting rolls and bending punch*

### **Charpy impact test**

The notched bar impact test is used to determine the tendency of a material to behave in a brittle manner. This type of test will detect differences between materials which are not observable in a tension test. The specimen will be destructed.

*Device: Pendulum impact testing machine Zwick RKP 450 GE with an Pendulum head 300 joule*

### **Dynamic tests with uniaxial and multiaxial testing devices**

Serves to determine the fatigue resistance (stress-number curves) of metallic samples and polymers, components, and implants using uniaxial and multiaxial dynamic tests).

*Devices: 5 uniaxial hydraulic rams with «Schenk» hydraulic cylinders and «Inova EU3000» digital control  
1 MTS 858 Mini Bionix multiaxial servo-hydraulic testing device*

### **Rotating beam fatigue tests (non-accredited service)**

The rotating bending fatigue test serves to determine the fatigue strength under reversed bending stresses of metallic samples allowing for specific surface structures, and to investigate the adhering strength of coatings on metallic and synthetic samples.

*Device: BIG1 Rotating bending testing device (self-made, corresponds to DIN EN ISO 7500-1)*

### **Vickers hardness test**

Hardness test of metallic and non-metallic materials according to the test procedure of Vickers.

*Device: Vickers hardness testing device UHL VMH-002V (up to HV2)*

### **Shore hardness test**

Hardness test of polymers and rubbers according to the test procedure of Shore A und D.

*Devices: Type A Durometer / Type D Durometer*

### **Coating thickness measurement (eddy current and magnetic induction method)**

Non-destructive coating thickness measurement according to the eddy current method (DIN EN ISO 2316) and the magnetic induction method (DIN EN ISO 2178). Due to automatic substrate material recognition and the integration of both methods, non-magnetic coatings on steel and iron (Fe) and nonconductive layers on non-ferromagnetic metals or non-conductive substrates can be measured. The method permitted a determination of the coating thickness in a range of 0 – 2000  $\mu\text{m}$  (Fe) respectively 0 – 1200  $\mu\text{m}$  (NFe). With a measurement stand a precise and exact measurement even on small samples is possible.

*Device: Fischer Dualscope FMP20*

### **Electrical conductivity measurement of non-ferrous metals**

Fast, non-destructive and precise measurement of the electrical conductivity of non-ferrous metals using various frequencies. Determination of the hardening condition of precipitation hardenable alloys (e.g. Al, Cu).

*Device: Fischer Sigmascope SMP10*

### **Particle analysis**

The particle analysis is a way to qualitatively or quantitatively determine the particle size distribution in powders, suspensions and emulsions. Furthermore, the characterisation of particle debris from wear tests is viable. Different measuring principles are available:

In the Laser Diffraction principle, the particles are irradiated by a laser beam. A characteristic annular intensity distribution is produced after transmission of the specimen by partial diffraction. This intensity distribution is detected and transformed to a particle size distribution by calculation (Theory of Mie or Fraunhofer). The principle allows for the qualitative determination in a range of 0.017– 2000  $\mu\text{m}$  (wet) or 0.04 – 2000  $\mu\text{m}$  (dry) respectively. Ultrasonic agitation aids for a good dispersion.

Particle size and shape can be determined by filtration and documentation as well.

Devices: *Beckman Coulter LS 13320 (Laser Diffraction principle)*

*Particle characterization by filtration and documentation using light microscopy and SEM*

### **Climatic chamber tests**

The climatic chamber test serves to condition, precipitate and age samples, components and prefabricated parts on defined climatic conditions (temperature, humidity) in order to assess their resistance and/or implement possible subsequent tests.

Device: *Feutron climatic chamber type KPK 200*

### **Washing, sterilization and cleaning tests of medical devices**

It serves to verify and validate the application requirements of medical devices regarding washing, sterilization and cleaning, handling and aging. Investigations may include determination of residual contamination, material aging, stress-cracking susceptibility, corrosion or operability according to standards or customers specification.

Devices: *«Tuttnauer 2540E» autoclave / «MIELABOR G7783» automated laboratory washer / «WTB Binder» drying oven / Miele Professional Washer-disinfector G 7836 CD*

### **Contact angle measurement**

A measurement of the contact angle allows a quick characterisation of a surface. Is it hydrophilic or hydrophobic? Are there contaminations? Did a coating work or not? Using two different test liquids, the surface energy can be determined.

Device: *Surftens universal (OEG GmbH, Frankfurt, Germany)*

### **Roughness measurement (non-accredited service)**

Contactless measurement of the topography using a confocal microscope. From the topography, the roughness parameters can be calculated using extracted profiles or areas.

Device: *Confocal microscope  $\mu\text{Surf}$  (NanoFocus AG, Germany)*

### **Crack detection / penetrant testing**

Liquid penetrant examination to detect flaws with openings to the surface (cracks, overlaps, wrinkles and pores) for all materials that are resistant to the penetrant and do not have high porosity.

Device: *red penetrant of fluorescent, solvent based cleaner and developer*

### **Finite element analyses (FEA)**

The Finite Element Method (FEM) or the Finite Element Analysis (FEA) serves to determine the tensions, elongations or temperatures in prefabricated parts, components and products. Based on geometric data and/or CAD models, this analytical, computer-based calculation method permits structural and/or thermal analyses and optimisations as well as the presentation of the results as individual values or as distribution pictures.

Device: *High-performance PC with «ANSYS» analytical software V. 15.0*

### **Optical 3D deformation analyses (non-accredited service)**

Optical measurement technology for time-resolved displacement and strain analysis on surfaces of materials and components under static or dynamic load. Can be used with any testing machine as long as the surfaces to be measured are visible.

Device: *Optical 3D Deformation Analysis device GOM Aramis 2M*

### **Failure analyses**

This analysis consists in establishing the causes of damage and in proposing the improvement measures by means of investigations and technical expert opinions of the damages of the medical products (particularly orthopaedic and traumatologic implants and instruments), the technical products and the components as well as a concise and comprehensible documentation of the investigation results and conclusions.



## TRIBOLOGICAL INVESTIGATIONS

### **Pin-on-disk wear test (OrthoPOD)**

The OrthoPOD 6-station test setup and weight measurement are used for screening tests to investigate and determine the wear behaviour of two gliding partners in a freely selectable type of burden and motion sequence.

Devices: 2 OrthoPOD™ pin-on-disk test setups, AMTI, Watertown, USA

### **Hip Simulator / Spine Simulator**

Wear test of implants for intervertebral disc replacement according to ISO 18192 and hip simulation tests according to ISO 14242-1.

Devices: Hydraulic 6-station Hip and spine simulator, EndoLab, Thansau, DE

## ADVICE / VALIDATION / LITERATURE\*

\* non-accredited services

### **Advisory, planning of investigations and validation**

Consulting services and training regarding all technical and scientific expertise and tests, in which the RMS Foundation is involved through its research activities, studies and services themselves. Investigation planning of surgical instruments and implants. Advice on validations.

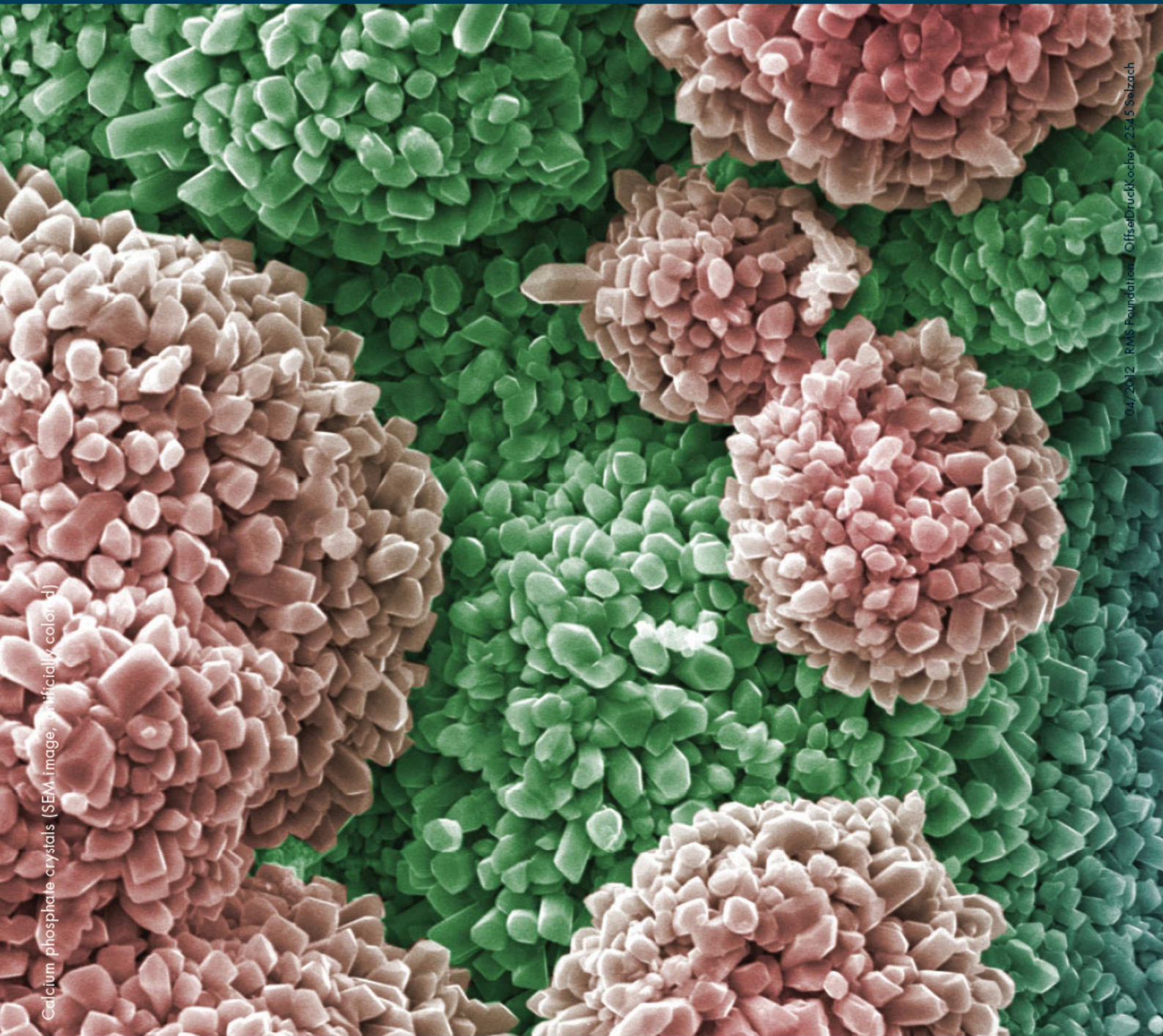
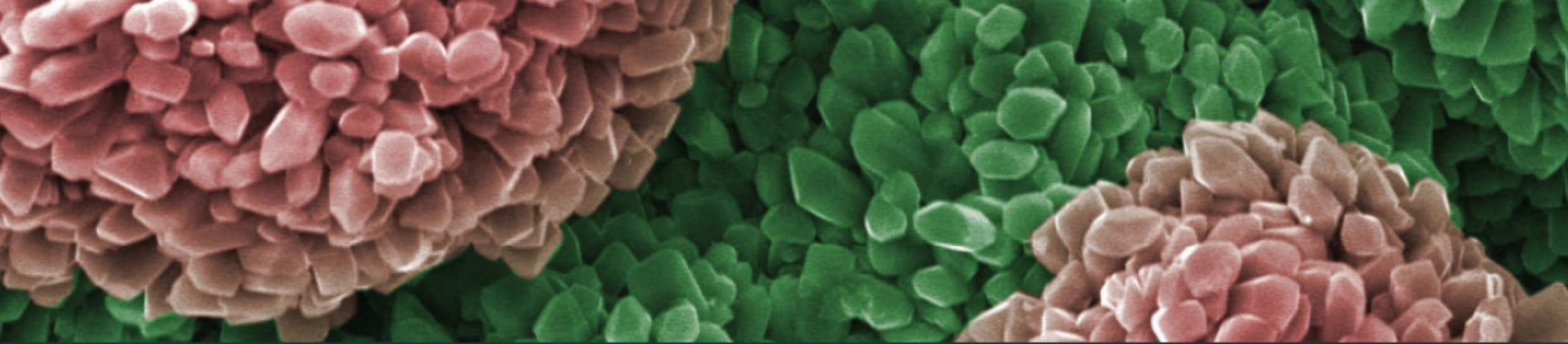
### **Cleanliness of implants / cleaning validation**

On the subject of "cleanliness of implants" both consulting services and chemical analyses are offered. We advise our clients on cleaning issues and process validations. We support you from the planning of the validation studies to the final report. In addition, we assess or develop risk analyses, evaluate the IQ and OQ documents or conduct performance qualification (PQ) studies, including the preparation of customized test specimens, appropriate staining and chemical analysis.

### **Literature reviewing (ISO 10993-1)**

Search and critical evaluation of relevant literature on medical, material and process related topics based on customer specifications.





Calcium phosphate crystals (SEM image, artificially colored)

04/2012 RMS Foundation, OffsetDruckKocher, 25x5 Salzach