IMPLANT STUDY 2024-2026

Global Quality Assessment of Dental Implants by SEM+EDS

Testing performed according to new FDA Guidance
on performance criteria for the safety of dental implants*

STUDY PROTOCOL

and Details for Study Participants

Scientific Advisory Board:

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Dr. Dirk U. Duddeck (Charité University, Berlin, Germany)
Dr. Scott Ganz (Fort Lee, New Jersey, USA)
Dr. Birgit Hagenhoff (CEO Tascon GmbH, University Münster, Germany)
Dr. Pjotr Majewski (University Medical College Krakow, Poland)
Prof. Jaafar Mouhyi (University of Agadir, Morocco)
Dr Michael R. Norton (London, United Kingdom)
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Technical Implementation

medical materials research institute berlin
Max-Planck-Str. 3, 12489 Berlin-Adlershof
Accredited testing laboratory according to
ILAC MRA / DIN EN ISO/IEC 17025:2018

RESEARCH MADE IN GERMANY

background and aim

Over the past decade, more than 450 implants have been analyzed on behalf of the CleanImplant Foundation using the same SEM analysis protocol. Conclusive evidence from extensive clinical studies corroborates the suspicion that residues on sterile-packaged implants, particularly organic particles originating from production or packaging processes, play a significant role in incomplete osseointegration or early bone loss. These studies have shown that neither the CE mark nor the US FDA clearance is a reliable indicator for the cleanliness of sterile dental implant surfaces.

However, suppliers of high-quality implants may find it increasingly difficult to assert themselves in a highly competitive market. The CleanImplant Project aims to promote these quality-oriented companies. With this Implant Study 2024-2026, CleanImplant conducts a new global quality assessment of dental implants again, providing an overview of the production quality of all major players in this market.

Considering your market presence and your unwavering commitment to achieving the best clinical results, the CleanImplant Scientific Advisory Board has selected your implant system for the current sample group.

The authors of this study publish results in high-ranked peer-reviewed journals. Additionally, excerpts will be available in high-circulation scientific journals, presented at various congresses worldwide, and shared on social media, supporting dentists worldwide in gaining orientation when deciding on a clean implant system. After all, the excellent results of this independent comparative study may serve as a powerful message for worldwide advertising purposes.

who is conducting this study?

This worldwide quality assessment study on dental implants is being conducted by the CleanImplant Foundation in cooperation with Charité University Medicine, Berlin. The CleanImplant Foundation was established as a non-profit organization in 2016 with the aim of providing unbiased information and guidance for dental practitioners on endosseous packaged dental implants sold worldwide.

An international Scientific Advisory Board of renowned experts, researchers and practitioners, supports this study and all scientific work of the CleanImplant Foundation:

- Professor Tomas Albrektsson; Department of Biomaterials; University of Gothenburg, Sweden
- Professor Hugo de Bruyn; ACTA University, Amsterdam, Netherlands
- Dr. Luigi Canullo; Private practice, Rome, Italy
- Dr. Scott Ganz; Private practices in Fort Lee, New Jersey and Manhattan, New York, USA
- Dr. Birgit Hagenhoff, CEO Tascon GmbH, Visiting Pofessor of the University Münster, Germany
- Dr. Piotr Majewski, University Jagiellonski Medical College Krakow, Poland
- Professor Jaafar Mouhyi; International University of Agadir, Morocco
- Dr. Michael R. Norton, President of the AO 2017-2018; Private practice, London, UK
- Dr. Amit Patel, Honorary Clinical Lecturer at the University of Birmingham Dental School, UK
- Professor Ann Wennerberg, Faculty of Medicine at the University of Gothenburg, Sweden

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how to benefit from participating

The CleanImplant Foundation's vision has been to raise awareness of the varying levels of surface cleanliness of implants on the market. By adhering to a standard of duty and care, companies are acknowledged as pursuing a path to excellence for end-users and patients.

Those manufacturers with implant systems selected in CleanImplant's worldwide quality assessment study have several options for cooperation and support. The extent of any collaboration will not affect the results of the technical analysis conducted by independent and accredited testing laboratories.

The Foundation appreciates participants actively supporting the research funding, thus expediting the completion of the study. All active participants receive a comprehensive technical report of SEM/EDS analyses, in accordance with ISO 22309, for their respective samples, including high-resolution images and detailed reports, ahead of schedule and prior to publication. All high-resolution SEM images and data provided can be used for commercial purposes.

performed along the lines of new FDA performance criteria

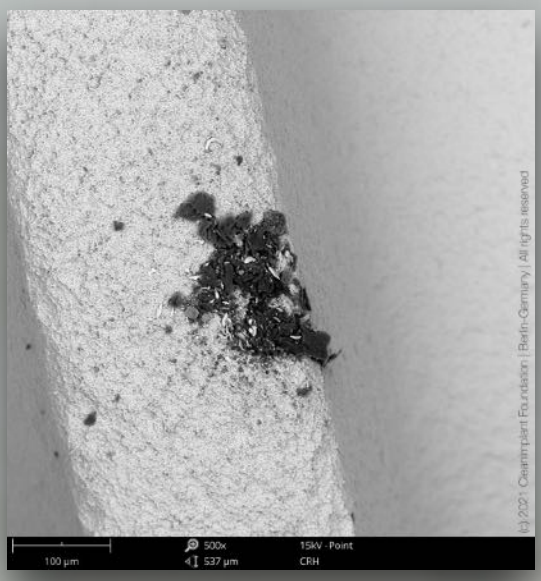
On October 15, 2024, the FDA released **new guidance for the dental industry***. FDA's "Performance criteria for the safety of Endosseous Dental Implants", demands a "**Surface Cleanliness Analysis**" providing "analysis of the surface of the implant body, using scanning electron microscope (SEM) and energy dispersive X-ray spectroscopy (EDS), that allows for magnified images of the implant surface and determination of the surface elemental composition. The magnified images should be of sufficient magnification to show the entire representative surface of the implant." We are grateful that the **FDA acknowledges the comprehensive testing procedure** developed by our group already in 2016 for a long series of quality assessment studies.

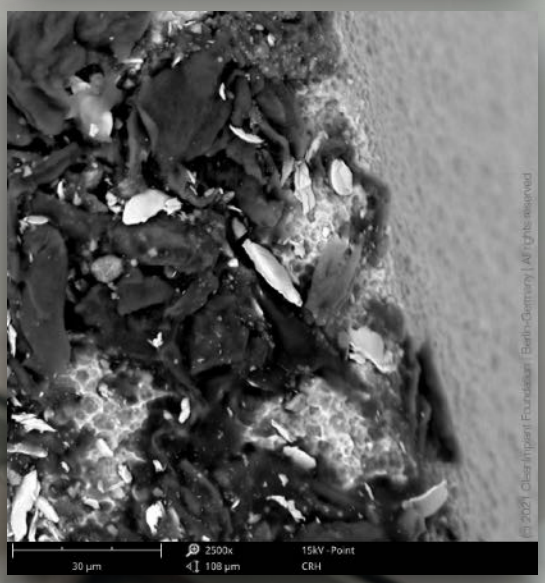
*) https://www.fda.gov/media/182616/download

Please feel free to contact us for more information about supporting the Foundation's work, covering the technical and organizational costs of conducting this large-scale study, and becoming an active collaborator in shaping safer implantology. Terms and conditions for active participation can be found on the feedback page at the end of this brochure. A sample study contract is available upon request.

key advantages for active participants

- Complimentary **20-30 pages testing report according to FDA recommendations**, provided by an officially accredited testing laboratory with **detailed data** directly after performing the technical analysis and before publication of the test results
- Set of **SEM images in extremely high resolution for marketing activities**
- **Validation of your internal quality management** with an unbiased, independent SEM/EDS analysis from an external source accredited according to ILAC MRA DIN EN ISO/IEC 17025:2018
- Comprehensive **500+ pages final report of the Implant Study 2024–2026** with data on all dental implants examined after study completion (PDF)
- PDF Report of the preceding Implant Study 2021-2023, **506 pages with 800 SEM images** in high resolution and elemental analyses showing **data on 80 implant systems from 55 brands**





All laboratories working in the framework of CleanImplant-supported research projects are subject to regular audits and multiannual reassessments by external, independent accreditation bodies. Registration number of the German Accreditation Body DAkkS for the medical materials research institute is D-PL-21057-01-00.

study protocol

Highest Standards for the Implant Analysis

All collected samples are subjected to the same quality analysis protocol performed by the medical materials research institute, Berlin-Adlershof, Germany. In order to provide a setup that complies with the highest standards of scientific research, this independent laboratory is officially accredited by the German accreditation body DAkkS according to

- ILAC MRA / DIN EN ISO/IEC 17025:2018 (general requirements for the competence of testing and calibration laboratories). This includes the quality standard according to
- DIN EN ISO 9001:2015 and the implementation of international standards for microbeam analysis scanning electron microscopy, such as
- ISO 16700:2016 (Guidelines for calibrating image magnification)
- ISO 14595:2014 (Guidelines for the specification of certified reference materials)
- ISO 22309:2015 (Quantitative analysis using energy-dispersive spectrometry EDS).

ISO Class 5 Cleanroom Environment DIN EN ISO 14644-1

The unpacking of the implants themselves, the fixation of the samples on a specimen holder, and even the imaging process and elemental analysis by the scanning electron microscope take place in a particle-free environment that meets class 100 cleanroom requirements according to United States Federal Standard (US FS) 209 and ISO class 5 according to DIN EN ISO 14644-1.

Scanning Electron Microscopes

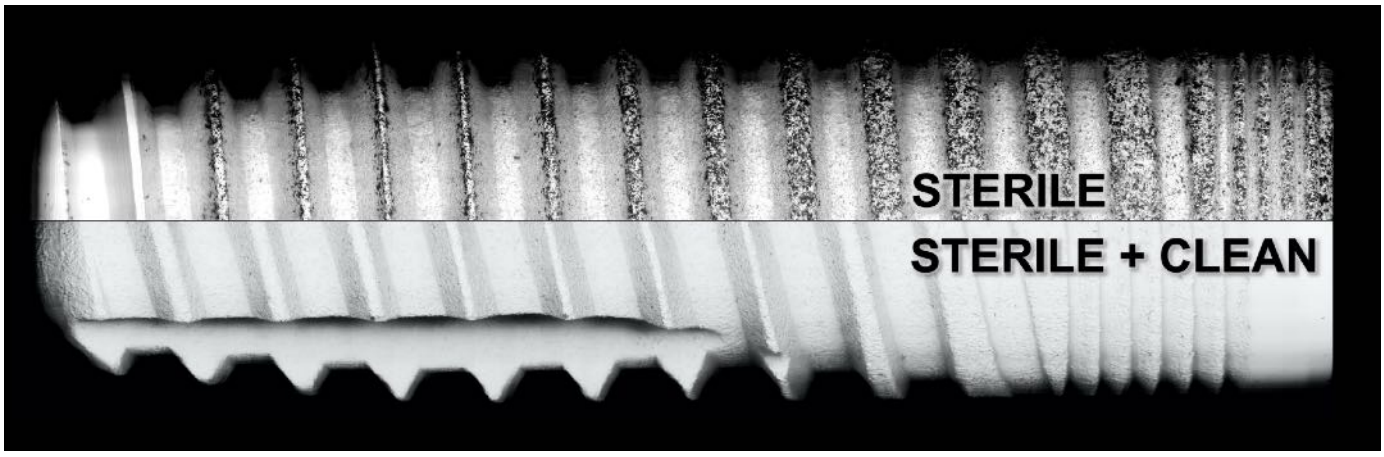
The scientific workstations in the testing laboratory are Phenom proX and Phenom XL Scanning Electron Microscopes provided by Thermo Fisher Scientific, equipped with a high-sensitivity backscattered electron detector that allows compositional and topographical imaging modes. Energy Dispersive X-ray Spectroscopy (EDS) analysis is performed with a thermoelectrically cooled Silicon Drift Detector (SDD). Active area: 25mm^2; Energy resolution Mn Kα ≤ 140 eV; Processing capabilities: Multi-channel analyzer with 2048 channels at 10 eV/ch; Max. input count rate: 300,000 cps.

Full-size, High-resolution SEM Mapping Images

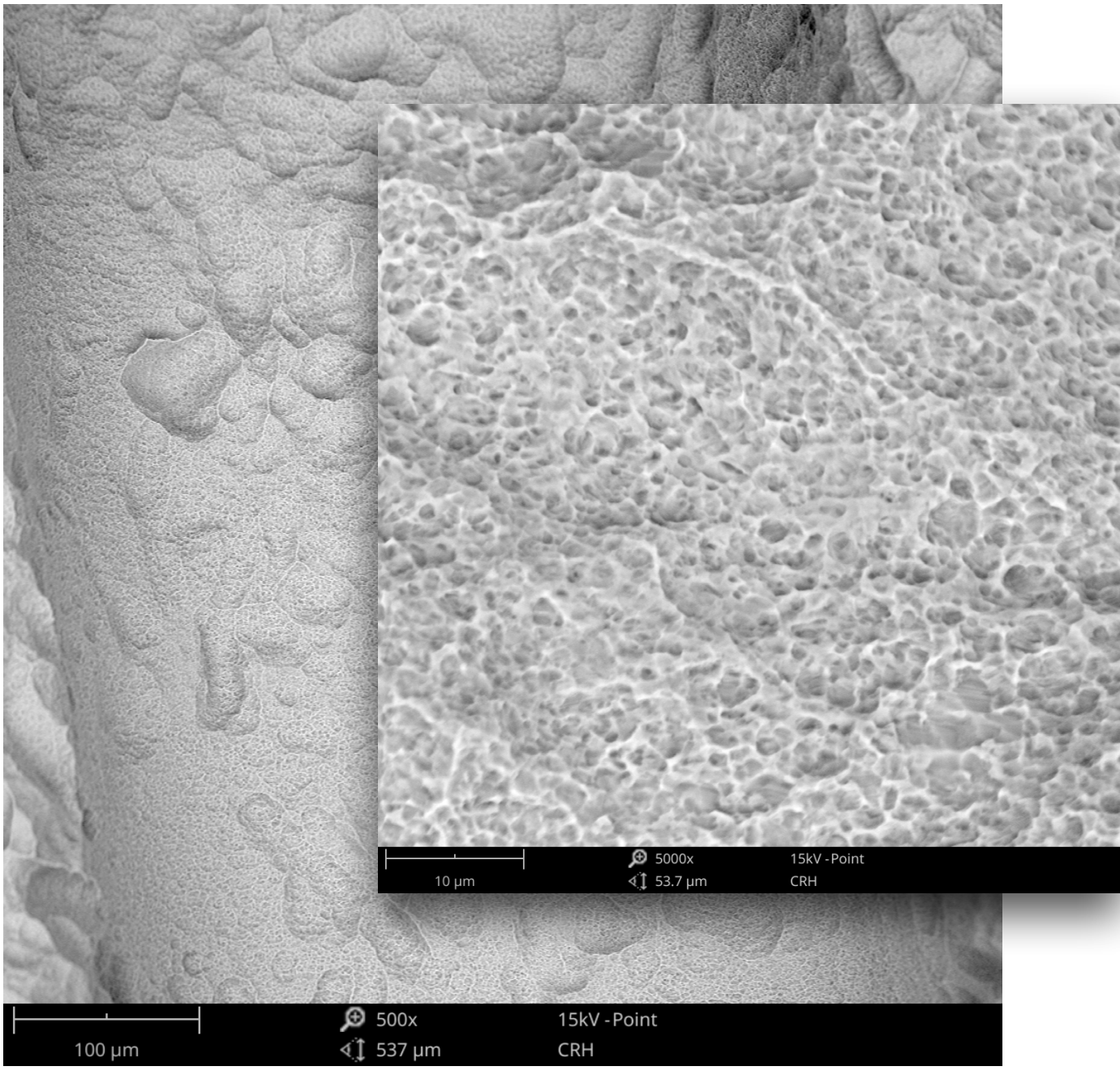
Implants are scanned at a magnification of 500x from shoulder to apex in the “Image-Mapping” mode. This technique produces up to 600 single high-resolution SEM images that are digitally composed to one large image with an extreme high resolution, the FSHR image (Full-Size High-Resolution). Mapping images of implant samples in this study show the complete surface at an angle of view of 120°. Thus, the detailed report of every implant provides information not only on single sections or small areas of the sample but always a complete and precise overview of the implant surface. The composed FSHR mapping image allows the laboratory to count particles in the visible field and identify areas of interest for subsequent spot analyses.

Detailed SEM-Imaging and Analysis into the sub-micron Range

Scanning electron microscopy (SEM) enables the topographical evaluation of the implant surface. The high-sensitivity backscattered electron (BSE) detector produces material-contrast images of implants made of titanium, titanium alloy, and zirconia up to a magnification of 5,000x, showing particles as small as 0,5 µm in diameter. BSE imaging provides additional information about the implant sample, such as the chemical nature and allocation of different remnants or superficial contaminants.



Example: Two sterile dental implants with a different level of cleanliness (FSHR imaging)

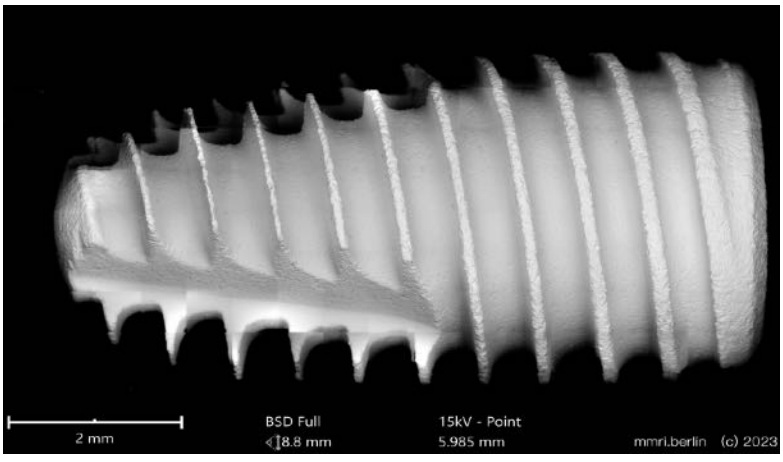


Example: Sterile and clean implant surface in SEM BSE-mode, 500x (left) and 5,000x (right)

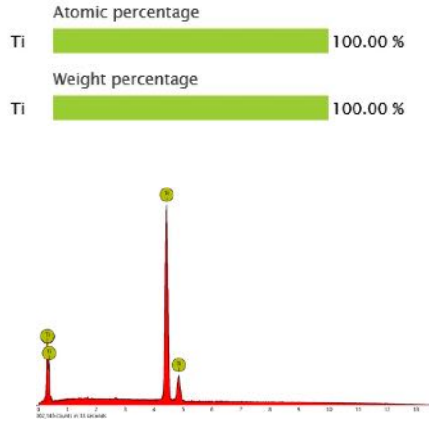
Elemental Analysis

Energy Dispersive X-ray Spectroscopy (EDS) analyzes X-rays generated by the electrons of the electron beam (CeB_6 electron source) while they are interacting with the sample. Each element emits specific X-ray peaks. The element identification software identifies even hidden elements within the sample via spot mode analysis. All results are verified using iterative peak stripping deconvolution.

For each tested implant, area analysis and multiple spot analyses are performed (elemental analysis of spots and areas by EDS). The area analysis covers the entire implant area in the scanning electron microscope's focus. For a spot analysis, the electron beam is focused on a specific area to get information about selective accumulations on the implant surface.

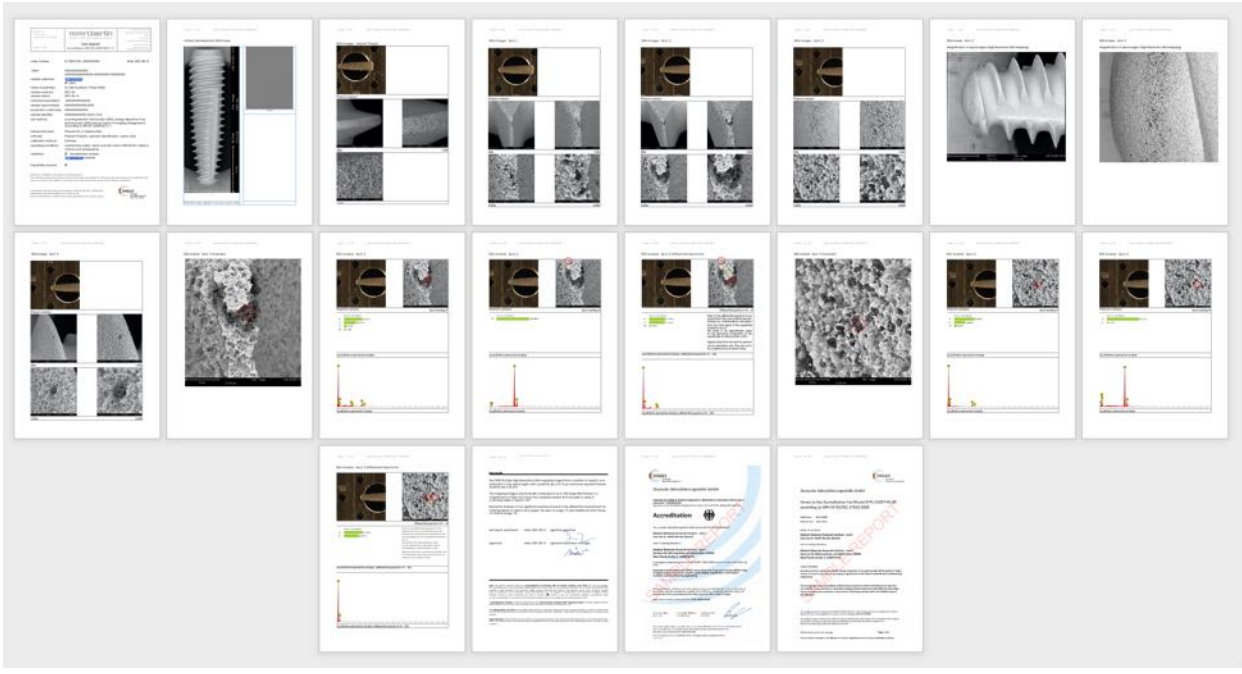


Full-size high-resolution SEM mapping image of a clean implant.



EDS data of Ti Gr4 implant (left)

Comprehensive testing report of an independent implant sample analysis



Example of a comprehensive testing report with SEM image magnifications up to 5,000x and elemental analysis by Energy Dispersive X-ray Spectroscopy - EDS - according to ISO 22309:2015. Tests performed at MMRI.BERLIN, (Medical Materials Research Institute, Berlin-Adlershof, Germany), The independent testing laboratory is officially accredited according to DIN EN ISO/IEC 17025:2018.

implant sample specification shipping address

The study requires

- **2 original packaged sterile implant samples of every type**
- **year of production 2024-2026**
- **preferred length 10-13 mm**
- **preferred diameter 3-4 mm.**

Contact: For further questions call +49 (0) 30 2000 301 90
or send an email to study@cleanimplant.org

Shipping address for all implant samples:

MEDICAL MATERIALS RESEARCH INSTITUTE
c/o LFM Labor fuer Mikroanalytik
Max-Planck-Str. 3
12489 Berlin
Germany

Note: To avoid customs if samples were sent from outside the EU, please add a **proforma invoice** with a value of 1 Euro/sample and add **“for testing only, not for medical purposes”**.

response form

Please send a FAX to: +49 30 221 872 37

or send a PDF scan to: study@cleanimplant.org

Please select your study participation here and send us your feedback.

☐ Yes, **we will join this study as active participants**. Please send us the contractual agreement for this study. The fee for one implant type is € 2,800 (each additional type € 1,800, plus 10 % overhead).
We will receive:

- Comprehensive 20-30 page SEM/EDS **testing report in accordance with DIN ISO 22309**
- Complete set of high-resolution **SEM images for commercial purposes prior to publication**
- 500+ page report of the Implant Study 2024-2026 as a PDF after completion of the study
- **Report of the preceding Implant Study 2021-2023, 506 pages with 800 SEM images** in high resolution and elemental analyses showing data on **80 implant systems from 55 brands**

☐ We **support this study as a passive participant** and will provide **two samples of one of our implant types free of charge**. We will receive brief information about the testing results via email, along with a PDF copy of any scientific publication containing the results for our implant samples.

☐ (Optional) As a passive participant in the current study, we hereby order the 506-page report of the Implant **Study 2021-2023** (PDF only) with data of 80 implants (€ 980). Please contact us.

☐ (Optional) As a passive participant, we hereby order a PDF copy of the **final report of the Implant Study 2024-2026** with data of approx. 100 implants on more than 500 pages, including published testing results of our samples provided (€ 1,980). Please contact us.

☐ **We are interested in learning more about this project and the CleanImplant Trusted Quality Seal**. Please contact us and send more information to our address below.

☐ **We are not interested in a collaboration.** Please order the requested test samples for this quality assessment study through one of our distributors.

Contact details: (please fill out with company name, responsible manager, email, phone etc.)

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