

CleanImplant Foundation Trusted Quality seal: More manufacturers prove the production quality of their implant systems

CleanImplant Foundation provides dentists and patients with guidance for clean dental implant systems of titanium and zirconia

After the “Astra Tech EV” by Dentsply Sirona was awarded this March, the coveted seal for Trusted Quality has now been given to two other implant systems: The renowned implants, “SuperLine” by Dentium and “INVERTA” by Southern Implants are now welcomed into the family of certified clean implants. The scientifically based seal of quality, which underlines the first-class surface purity of dental implants, is only awarded by the CleanImplant Foundation’s Scientific Advisory Board after a rigorous peer-reviewed analysis and testing process.

“This award is an objectively transparent proof that colleagues are using a residue-free medical device for their patients by manufacturers who implemented the highest quality standards,” explains Dr Dirk U. Duddeck, Founder and Head of Research at CleanImplant. To obtain this valid, objective proof, a so-called “five step approach” was established in cooperation with the eight-member Scientific Advisory Board:

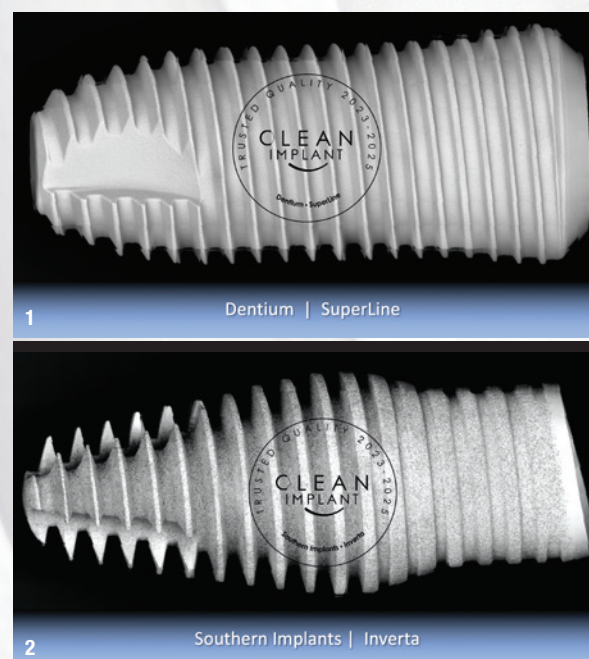


Fig. 1: SEM image SuperLine implant—Dentium. **Fig. 2:** SEM image INVERTA implant—Southern Implants.

CleanImplant Trusted Quality seal | Five step approach

STEP 1	Neutral sampling of five implants	Batch-spanning random sampling: Three implants are ordered ex-factory, and two implants of the same type are provided via mystery shopping from practices.
STEP 2	Unpacking and scanning under clean room conditions	All five collected samples are carefully unboxed, mounted, and scanned in a clean room environment according to Class 100 US Fed. 209, Class 5 DIN EN ISO 14644-1.
STEP 3	Externally audited process of analysis	SEM imaging and elemental analysis (EDS) are performed according to DIN EN ISO/IEC 17025 accreditation process (competence of testing and calibration laboratories) with external audits and multi-annual re-assessments.
STEP 4	Full-size and high-resolution SEM images	A special full-size, high-resolution SEM image—digitally composed of more than 360 single SEM images in a magnification of 500x—always shows the implant surface from shoulder to apex.
STEP 5	Peer-review process	Two members of the Scientific Advisory Board independently review the comprehensive report of analysis and sufficient clinical documentation or multi-annual PMCF studies (Post-Marketing Clinical Follow-Up) of the analysed implant type showing survival rates of more than 95% for the device or device family.

Every quality certification is valid only for two years and has to be renewed after this period. Other titanium-made implant systems that have been awarded the Trusted Quality seal are: Contact S (Biotech Dental), UnicCa (BTI Biotechnology Institute), (R)evolution (Champions-Implants), In-Kone (Global D), ICX-Premium (medentis medical), AnyRidge and BLUEDIAMOND (MegaGen), T6 (NucleOSS), Prama (Sweden & Martina). Other testing and analysis results are pending.

Selected ceramic implant systems also carry the “Trusted Quality” seal such as whiteSKY (bredent group), Patent/BioWin! (Champions-Implants), and SDS 1.2 and SDS 2.2 (Swiss Dental Solutions). Moreover, CleanImplant “Certified Production Quality” awards were received by the CeramTec Group and Komet Custom Made as contract manufacturers of ceramic implants.



Fig. 3: Dr Dirk U. Duddeck placing an implant on the sample holder of the scanning electron microscope.

After five consecutive quality assessment studies on dental implants, the Foundation has SEM data and test results of more than 300 different implant types on file. All tests have been performed exclusively by officially accredited testing laboratories. Dentists can request reliable information on the cleanliness of their preferred dental implant system. With 150,000 subscriptions from dental professionals, the CleanImplant Foundation has become a grassroots movement on social media. More and more dentists are actively supporting the CleanImplant Foundation. Certified as "CleanImplant Certified Dentists", they pass on the trust they gained in the products to their patients and referring dentists.

The independent **CleanImplant Foundation** was founded as a non-profit organisation in Berlin in 2016. In cooperation with renowned universities, the foundation regularly coordinates worldwide quality assessment studies of dental implants and awards the "Trusted Quality" seal to particularly clean implant types following a strict peer-review process to generate independent and meaningful data concerning the cleanliness/contamination of implant surfaces of sterile-packaged implants. All samples are tested exclusively in specialised testing laboratories officially accredited according to DIN EN ISO/IEC 17025:2018. CleanImplant also certifies implantologists as well as dental centers, thus increasing the confidence of referring clinicians, dentists and patients. More information: www.cleanimplant.org

Dentium has provided best products to dentists for 22 years since its establishment, operated a production plant in the United States for the first time in the domestic industry in 2004, and has obtained the certificate by MFDS of major overseas countries, including the US FDA. Based on world-class technology and reliable products, it is Korea's representative implant that is exported to more than 70 countries around the world. More information: www.dentium.co.kr

Southern Implants is a leading provider of innovative oral reconstruction products. The company focuses on providing site-specific, dental implant treatment solutions to advanced professional users who want more choices. Southern's expertise in research, development and precision manufacturing positions it to efficiently commercialise innovative treatment solutions that reduce treatment times and improve patient outcomes. Established in 1987 and privately owned, Southern Implants is headquartered in South Africa with a global distribution network. More information: <https://southernimplants.com>

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