

“Clean” medical products

After the “Astra Tech EV” by Dentsply Sirona was awarded already 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:

CleanImplant Trusted Quality Seal – Five step approach

STEP 1	Neutral sampling of 5 implants	3 implants are ordered ex-factory + 2 implants of the same type are provided via mystery shopping from practices.
STEP 2	Unpacking and scanning under clean room conditions	All 5 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.



Fig. 1: SEM image SuperLine implant—Dentium. **Fig. 2:** SEM image INVERTA implant—Southern Implants. **Fig. 3:** Dr Dirk U. Duddeck placing an implant on the sample holder of the scanning electron microscope.

Every quality award is valid only for two years and has to be renewed after this period. Currently, the following implant systems also carry the “Trusted Quality Seal”: Kontakt S (Biotech Dental), whiteSKY (bredent group), UnicCa (BTI Biotechnology Institute), (R)evolution and Patent/BioWin! (Champions-Implants), In-Kone (Global D), ICX-Premium (medentis medical), AnyRidge and BLUE-DIAMOND (MegaGen), T6 (NucleOSS), Prama (Sweden & Martina), SDS 1.2 and SDS 2.2 (Swiss Dental Solutions). Other testing and analysis results are pending.

Moreover, CleanImplant “Certified Production Quality” awards were received by the CeramTec Group and Komet Custom Made as contract manufacturers of ceramic implants.

More and more dentists are 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.

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