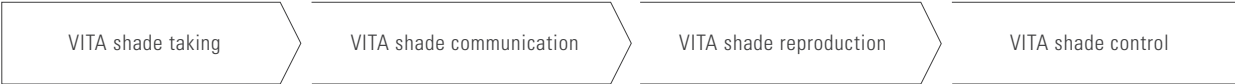
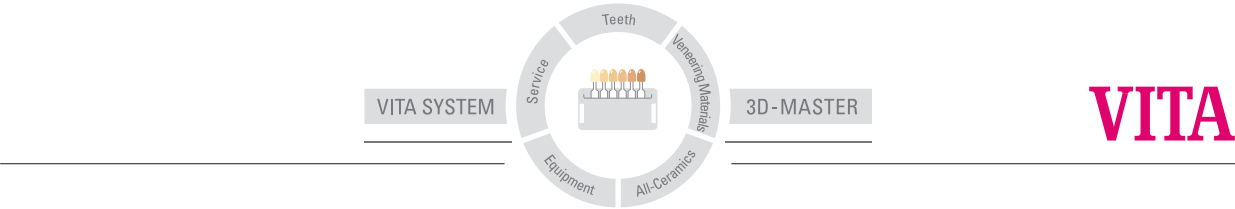


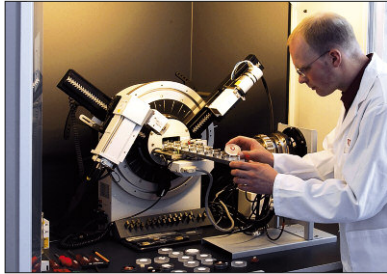
VITA Quality Report



Date of issue: 04.10



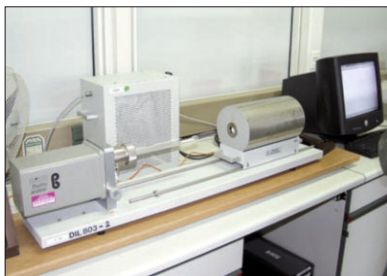
Overview of measures for quality assurance



When developing new products, the internal controls in the VITA laboratories are accompanied by tests of external laboratories.



The high-tech equipment for quality control of the VITA laboratories also includes a scanning electron microscope.



Thermal analyses are carried out to determine the coefficient of thermal expansion (photo source: DIGITAL_DENTAL_NEWS)

Many paths lead ... to the world of certified quality by VITA

Maintaining a certified quality management (QM) system is a matter of course for VITA Zahnfabrik as a quality-conscious manufacturer. This system includes measures for the improvement of products, processes and services alike. Moreover, each medical product by VITA is subject to a conformity assessment procedure which requires that all aspects of development and production comply with legal requirements and that complete documentation is ensured.

Among others, chemical and physical requirements in accordance with the ISO standards are adhered to. Moreover, all products need to go through a strict risk management process to safeguard a high level of biocompatibility. Clinical evaluation, continuous market observation including reporting any incidents, and a safety plan are also preconditions for CE labelling. Compliance with all requirements and high technical reliability are confirmed in a conformity assessment procedure.

Risk management

The comprehensive risk management system of VITA Zahnfabrik is taken very seriously and exceeds the legal requirements since - in addition to the specified product risks - numerous other requirements which are relevant for the user are assessed.

Manufacturing reliability

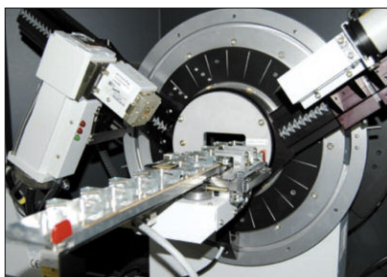
To be able to ensure consistently high quality for all VITA products, a comprehensive process qualification and validation program is maintained which, among others, includes visual inspections by production staff. Moreover a large number of tests are performed in the VITA laboratories which are equipped with high-tech equipment.

Material testing

As far as the production of material blanks for CAD/CAM techniques are concerned, the stringent material inspections are already applied when raw materials are received. These blanks are subject to a mineralogical analysis. Material characteristics such as the particle



Cracks in the material structure of CAD/CAM blanks can be detected in a computer tomograph.



An x-ray diffractometer is used to determine the crystalline components.



Universal testing machine for the 3-point bending test (photo source: DIGITAL_DENTAL_NEWS)

size distribution and the chemical composition are thoroughly examined. Employees always carry out visual inspections and tests of the blanks during the various stages of production. Even blocks which exhibit minor visual defects are immediately discarded. Detailed and comprehensive inspection plans are the basis for the determination of the exact physical-mechanical properties of the final products. Thermal analysis, for example, is used to measure the coefficient of thermal expansion of each lot. As far as the zirconium dioxide material VITA In-Ceram YZ is concerned, the accurate determination of the shrinkage factors in all three spatial dimensions is important for laboratory users.

Laboratory equipment

Among other systems, the modern equipment of the VITA test laboratories includes a scanning electron microscope and a computer tomograph to examine the homogeneity of materials and to make sure that any defects are eliminated. An x-ray diffractometer is used to analyze the crystalline components. Moreover, a universal testing machine is available to perform the standard 3-point bending test.

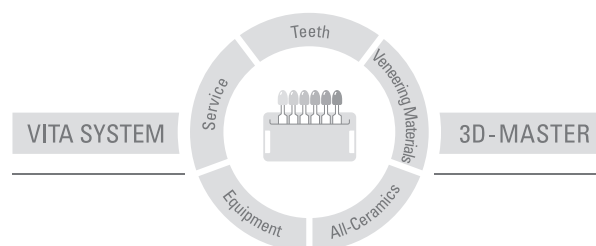
Improvement process

An internal CAPA (Corrective and Preventive Actions) program helps VITA employees to identify problems, learn from mistakes and to develop suitable options for optimization and to implement them. Within the scope of CIP (Continuous Improvement Process), employees decide which actions need to be implemented. For this purpose, employees analyze their responsibilities, prepare specific suggestions for improvement, implement the adopted measures and check whether the desired success can be achieved. The continuous improvement process covers the quality of products, processes and services.

Support / Services

High quality of support and services plays an important role for VITA Zahnfabrik. A broad course program is available to offer dental technicians and dentists practical basic and advanced training. The six service centers of VITA ensure regional proximity to interested persons. The Service Hotline staff supports dental laboratories and dental practices with technical questions.

With the unique VITA SYSTEM 3D-MASTER all natural tooth shades are systematically determined and completely reproduced.



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