The NIOM TESTED quality seal provides customer assurance and is an efficient tool for increased market response!

NIOM's program for quality evaluation of dental products is based on testing according to methods in relevant ISO standards or other documented test methods. Our accredited test laboratory guarantees accurate results for all categories of dental materials.

The NIOM TESTED quality seal confirms that the product meets the requirements of NIOM's evaluation.

The NIOM TESTED quality seal in colour or black and white, can be used with the tested product to which the seal is assigned. The seal may be applied either to the products, on the packaging, in the instruction manual or in marketing of the products.

The NIOM TESTED quality seal printed on the product.

Director of the Swedish optical ergonomic solutions company Merident Optergo, Mr Per Johan Pettersson, chose NIOM to document his new product "MO Wing" before releasing it on the dental market.

– We chose NIOM to run tests on our product and achieved the NIOM TESTED quality seal for our product. We found NIOM's analysing process to be both a timesaver in documenting our product as well as being very cost efficient. The NIOM TESTED quality seal has proven to be an efficient sales tool for our new product, which is already turning out to be a success story in the Nordic countries. Next step is the European continent, Mr Pettersson says.

Accredited laboratory at your fingertips

We believe that high quality of dental materials is vital, for the patient, for the dentist and for the manufacturer. NIOM's specific testing modules provide great advantage for your product upon achieving the NIOM TESTED quality seal.

Based on our knowledge of dental materials and long experience in material testing, we have highlighted the essential test methods to assess safe and functional biomaterials. Material scientists and dental clinicians have agreed on the necessary tests to ensure that both material quality and clinical aspects are covered.

Products will be analysed and screened for the most important properties of each specific product group, limiting the test methods to those that we believe will demonstrate the quality of the material.

NIOM has modern and well-equipped laboratory facilities. The institute is accredited according to ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories. This ensures high-quality results promptly delivered with confidentiality.

The NIOM TESTED quality seal is issued with a verification document identifying the product and the category of the test, thus confirming that the product meets the requirements of NIOM's quality evaluation.

NIOM has researchers and scientists with inter-disciplinary competence covering all aspects of dental biomaterials – clinical dentistry, biology, toxicology, chemistry and physics – allowing an understanding of both biocompatibility and technical properties.

Enhance your product reliability – with confidence and ease!

Confidence in your products and innovations is crucial for market performance and sales. When you document your products' reliability and quality you are taking the obvious steps towards this belief. Label your products with this confidence – and you are one step ahead!

Composites
(Light-cured, polymer-based)

	Test methods	Requirements
	Flexural strength, ISO 4049 7.11	Minimum 80 MPa (Type 1), minimum 100 MPa (Type 1, Class 2, Group 2) or minimum 50 MPa (Type 2) (ISO 4049 5.2.9)
	Colour stability, ISO 4049 7.13	Not more than a slight change in colour upon visual inspection after water sorption and irradiation (ISO 4049 5.4)
	Depth of cure, ISO 4049 7.10	Minimum 1.5 mm or not more than 0.5 mm below the value stated by the manufacturer, minimum 1 mm if the material is labelled as opaque (ISO 4049 5.2.8)
	Water sorption and solubility, ISO 4049 7.12	Sorption: ≤ 40 µg/mm^3, Solubility: ≤ 7,5 µg/mm^3 (ISO 4049 5.2.10)

Luting materials
(Dual-cured or chemical cured, polymer-based)

	Test methods	Requirements
	Film thickness, ISO 4049 7.5	Not more than 10 µm above the claimed value by the manufacturer, or in any event not greater than 50 µm (ISO 4049 5.2.2)
	Working time, ISO 4049 7.7	At 60 s starting after the completion of mixing: The material shall be capable of forming a thin layer with no detectable change in homogeneity (ISO 4049 5.2.4)
	Setting time, ISO 4049 7.8	Not more than 5 minutes (Class 1) or not more than 10 minutes (Class 3) (ISO 4049 5.2.5 and 5.2.6)
	Water sorption and solubility, ISO 4049 7.12	Sorption: ≤ 40 µg/mm^3, Solubility: ≤ 7,5 µg/mm^3 (ISO 4049 5.2.10)

Root-canal sealers
(Dual-cured or chemical cured)

	Test methods	Requirements
	Flow, ISO 6876 5.2	Diameter not less than 17 mm for the prepared disc (ISO 6876 4.3.1)
	Working time, ISO 6876 5.3	Diameter from the flow test shall be not less than 17 mm at 15 s before the end of the stated working time (ISO 6876 4.3.2) or at 30 min if not stated
	Film thickness, ISO 6876 5.5	Not more than 50 µm (ISO 6876 4.3.4)
	Solubility, ISO 6876 5.6	Not more than 3.0 % by mass (ISO 6876 4.3.5)

Elastomeric impression materials

Test methods	Requirements
Working time, ISO 4823 9.3	Not less than stated in manufacturer's instructions, and at least 30 s longer than the time required to obtain a homogenous mix (ISO 4823 6.3)
Detail reproduction test, ISO 4823 9.4	Line width 75 µm (Type 0), 50 µm (Type 1), 20 µm (Type 2 and 3) (ISO 4823 Table 1)
Linear dimensional change test, ISO 4823 9.5	Maximum 1.5 % (ISO 4823 Table 1)
Elastic recovery test, ISO 4823 9.7	Minimum 96.5 % (ISO 4823 Table 1)

Metallic materials – Noble alloys (Type 3)

Test methods	Requirements
Chemical composition, ISO 22674 8.2	To a precision of 0.1 % (mass fraction) for all elements present and declared by the manufacturer in excess of 1.0 %, and for Ni in excess of 0.1 %. Identification of other elements present in excess of 0.1 % (mass fraction) (ISO 22674 5.1) Not more than 0.02 % (mass fraction) of cadmium or beryllium (ISO 22674 5.2.2)
Corrosion resistance, ISO 22674 8.5	Total metal ion release of maximum 200 µg cm^{-2} (ISO 22674 5.6)
Proof strength of 0.2% non-proportional extension, ISO 22674 8.3.3	Minimum 270 MPa (ISO 22674 Table 1)
If indicated for metal-ceramic restorations: Linear thermal expansion, ISO 22674 8.8	Shall not differ by more than 0.5 x 10^{-6} K^{-1} from the value stated by the manufacturer (ISO 22674 5.9)

Metallic materials – Base-metal alloys (Type 5)

Test methods	Requirements
Chemical composition, ISO 22674 8.2	To a precision of 0.1 % (mass fraction) for all elements present and declared by the manufacturer in excess of 1.0 %, and for Ni in excess of 0.1 %. Identification of other elements present in excess of 0.1 % (mass fraction) (ISO 22674 5.1) Not more than 0.02 % (mass fraction) of cadmium or beryllium (ISO 22674 5.2.2)
Corrosion resistance, ISO 22674 8.5	Total metal ion release of maximum 200 µg cm^{-2} (ISO 22674 5.6)
Proof strength of 0.2% non-proportional extension, ISO 22674 8.3.3	Minimum 500 MPa
If indicated for metal-ceramic restorations: Linear thermal expansion, ISO 22674 8.8	The value shall not differ by more than 0.5 x 10^{-6} K^{-1} from the value accompanying the package (ISO 22674 5.9).

Dental ceramics

Test methods	Requirements
Flexural strength, ISO 6872 7.3	As given in Table 1 in ISO 6872 according to the clinical indication of the product
Chemical solubility, ISO 6872 7.6	As given in Table 1 in ISO 6872 according to the clinical indication of the product
Radioactivity, ISO 6872 7.2	Not more than 1.0 Bq/g of U238 (ISO 6872 5.2.2)
If indicated for metal-ceramic or zirconia-ceramic restorations: Metal-ceramic bond characteri-zation, ISO 9693-1 6.4	The debonding/crack-initiation strength of the combination of zirconia material and veneering ceramic, or metallic material and veneering ceramic shall be greater than 25 MPa (ISO 9693-1 4.2)

Eye protection filters for use with curing lamps

Test methods	Requirements
Light transmittance	Less than 0.1% light transmittance in the wavelength region 390-525 nm

Artificial teeth for dental prostheses

(Synthetic polymer teeth)

Test methods	Requirements
Comparison with shade guide, ISO 22112 7.3	No perceptible colour difference compared with the manufacturer's shade guide or nominated shade guide. Blended teeth: no line of demarcation between incisal and cervical portions on the facial aspects of the teeth
Porosity of synthetic polymer teeth and other defects, ISO 22112 7.7	No porosity or defect, such as rough trimming, rough finish or visible impurities, on the coronal surfaces
Quality of bonding of synthetic polymer teeth to denture-base polymers, ISO 22112 7.11	Capability of bonding to heat-polymerized denture-base materials (only for anterior teeth). Cohesive fracture mode within the tooth or the denture-base polymer
Resistance to blanching, distortion and crazing of synthetic polymer teeth, ISO 22112 7.12	No blanching or distortion. No crazing with the exception of the ridge lap surfaces and the cervical portion of the teeth up to the cervical line

Base polymers - Denture base polymers

(Type 1 Heat-polymerizable materials and Type 2 Autopolymerizable materials)

Test methods	Requirements
Ultimate flexural strength, ISO 20795-1 8.5.3.5	Not less than 65 MPa (Type 1) and not less than 60 MPa (Type 2)
Flexural modulus, ISO 20795-1 8.5.3.5	At least 2 000 MPa (Type 1) and at least 1 500 MPa (Type 2)
Residual methyl methacrylate monomer, ISO 20795-1 8.8	Maximum 2.2 % mass fraction (Type 1) and 4.5 % mass fraction (Type 2). If lower values are claimed by the manufacturer: not more than 0.2 % mass fraction higher than stated
Water sorption, ISO 20795-1 8.9	The increase in mass per volume shall not exceed 32 µg/mm^3
Water solubility, ISO 20795-1 8.9	The loss in mass per volume shall not exceed 1.6 µg/mm^3 (Type 1) and shall not exceed 8.0 µg/mm^3 (Type 2)

Base polymers - Orthodontic base polymers

(Type 1 Autopolymerizable materials)

Test methods	Requirements
Fracture toughness with a modified bending test, ISO 20795-2 8.4	The maximum stress intensity factor shall be at least 1.1 MPa m$^{1/2}$
Fracture toughness with a modified bending test, ISO 20795-2 8.4	The total fracture work shall be at least 250 J/m^2
Residual methyl methacrylate monomer, ISO 20795-2 8.5	Maximum 5 % mass fraction The content claimed by the manufacturer shall not exceed the stated value by more than 0.2 % mass fraction
Water sorption, ISO 20795-2 8.7	The increase in mass per volume shall not exceed 32 µg/mm^3
Water solubility, ISO 20795-2 8.7	The loss in mass per volume shall not exceed 5 µg/mm^3

NIOM – your premier choice for testing of biomaterials

NIOM – Nordic Institute of Dental Materials – is a Norwegian, governmentally owned, independent test and research institute located in Oslo. Established in 1972, the institute has long experience in the testing of dental biomaterials and delivers high-quality results promptly.

Our vision: work to ensure that dental biomaterials are safe and functional.
Our values: knowledge – innovation – quality.

Contact us today for a quotation for testing your products!

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