

CERTIFICATE

Biological Safety

As medical devices, our DD Incisal X coloring liquids for coloring and individualizing of dental restorations are subject to legally stipulated national and international standards and guidelines. The CE mark proves that our DD Incisal X coloring liquids meet all requirements.

Scope:

DIN EN ISO 10993-1: Biological evaluation of medical devices

Device/material:

DD Incisal X

Manufacturer:

Dental Direkt GmbH
Industriezentrum 106-108
32139 Spenge
Germany

Tests performed:

We hereby confirm that all required tests for the evaluation of the biocompatibility have been performed according to the international standard DIN EN ISO 10993-1 "Biological evaluation of medical devices". Tests and evaluations were carried out by the accredited test laboratory „Medical Device Services – Dr. Rossberger GmbH" in Germany.

Remark:

Changes in material / impurities due to the finalization by the customer were not included in the evaluation.

Results:

The coloring liquids have been tested and evaluated according to DIN EN ISO 10993-1 for the intended use. The insolubility of the material is in compliance with the requirements of this standard. There is no evidence that hazardous effects will arise by release of leachable ingredients.

We hereby confirm the biocompatibility of "DD Incisal X".



Marcel Brüggert (Geschäftsführer / CEO)