

CERTIFICATE

Biological Safety / Toxicology

The DD contrast[®] veneering ceramic system is suitable for the aesthetic individualization of monolithic or minimally reduced dental crown and bridge constructions made of zirconia or lithium disilicate.

The CE-sign on our products shows the conformity to all regulations.

Scope:

ISO 10993-1: Biological evaluation of medical devices

Device/material:

DDcontrast[®]

Manufacturer:

Dental Direkt GmbH
Industriezentrum 106-108
32139 Spenge
Germany

Tests performed:

We hereby confirm that all required tests as proof of the biocompatibility have been performed according to the international standard ISO 10993-1 "Biological evaluation of medical devices".

Remark:

Changes in material / impurities due to the individual finalization by the dental technician were not included in the evaluation.

Results:

DD contrast[®] products have been tested and evaluated according to ISO 10993-1 for the intended use.

We hereby confirm the biocompatibility of "DD contrast[®]".



Uwe Greitens (CEO)