

CERTIFICATE

Biological Safety / Toxicology

Dental Direkt zirconia blanks for manufacturing dental restorations are medical devices and subject to strict regulatory guidelines. The blanks are monitored and controlled regularly. The CE-sign on our products show the conformity to all regulations.

Scope:

Biological safety – toxicology, EN ISO 10993-1, Directive 93/42/EEC

Device/material:

DDcubeONE[®]

DDcubeONE[®]ML

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 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:

Possible changes in material and impurities due to the finalization at the customer were not considered in the evaluation.

Results:

The material has been tested and evaluated according to 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 the material.



Gerhard de Boer (CEO)