

CERTIFICATE

Biological Safety / Toxicology

Dental Direkt's milling blanks "DD Bio Splint C" for manufacturing of splints, therapeutic splints, bite regulators and drilling templates are medical devices and subjected to strict regulatory guidelines. "DD Bio Splint C" blanks are monitored and controlled regularly. The CE-sign on our products show the conformity to all regulations.

Scope:

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

Device/material:

DDBioSplintC

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:

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

Result:

Dental blanks (DD Bio Splint C) have been tested and evaluated according to DIN EN ISO 10993-1 for the intended use. The insolubility of the blank 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 Bio Splint C".



Gerhard de Boer (Geschäftsführer / CEO)