

CERTIFICATE

Biological Safety / Toxicology

Dental Direkt's milling blanks "DD polyX ML" for manufacturing dental restorations are medical devices and subjected to strict regulatory guidelines. "DD polyX ML" blanks are monitored and controlled regularly. The CE-sign on our products shows the conformity to all regulations.

Scope:

ISO 10993-1: Biological evaluation of medical devices

Device/material:

DDpolyX 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".

Remark:

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

Results:

Dental blanks (DD polyX ML) have been tested and evaluated according to 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 polyX ML".



Uwe Greitens (CEO)