CERTIFICATE

SLS: VFS + DDC

MTT CYTOTOXICITY - ISO 10993-1, ISO 10993-5 & ISO 10993-12

Biological evalution of medical devices - part 5: tests for in vitro cytotoxicity

MANUFACTURER / COMPANY
DyeMansion GmbH
Robert-Koch-Straße 1
D-82152 Planegg, Munich
Germany

DATE OF ISSUE
July 29, 2020

Hereby we declare that all our cytotoxicity tests have been made by an accredited test laboratory. The associated certificates or test results can be provided on request. The obtained results are in accordance with **ISO Guidelines 10993-1, ISO 10993-5 and ISO 10993-12**.

Information on tested materials:

The tested SLS (Selective Laser Sintering) parts were treated as follows:

- ✓ **Cleaning** with the DyeMansion Powershot C
- ✓ **VaporFuse Surfacing** with the DyeMansion Powerfuse S using VaporFuse VF47 Eco Fluid
- ✓ **DeepDye Coloring** with the DyeMansion DM60

For the cytotoxicity tests either the selection of base dyes or the exact formulation was used. The test procedure for each material and color can be found in the table below.

The following used parts dyed with the following mixtures are **classified as not cytotoxic**:

MATERIAL CLASS	MATERIAL NAME	SUPPLIER	COLOR	TEST PROCEDURE
Polyamide 12 (PA 12)	EOS PA 2200	EOS GmbH	DM Black 01	Exact formulation

Philipp Kramer, CTO

Felix Ewald, CEO

This declaration is only valid for the tested materials under the specific handled conditions. The cytotoxicity properties of the listed elements may change depending on the modification of the current regulations, test methods, DyeMansion processes, the composition, or the compliance of the used plastic material. It is the responsibility of each customer to control the cytotoxicity effect of his final product according to the compliance requirements. Relevant information regarding products stewardship and occupational safety and health can be obtained from the Safety Data Sheet.

Status 04/2021. Data subject to change without notice. Please request latest data from team DyeMansion.

HOME OF A COLORFUL FUTURE.