



CERTIFICATE

SLS: VFS + DDC

IN VITRO SKIN IRRITATION - ISO 10993-1, ISO/TC 194 WG 8 IN REFERENCE TO ISO 10993-10 & ISO 10993-12

Test on medical devices using reconstructed human epidermis (RhE) EpiDerm™

MANUFACTURER / COMPANY

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Hereby we declare that all the skin irritation 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 10993-1, ISO/TC 194 WG 8 in reference to ISO 10993-10 & 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
- ✓ **DeepDye Coloring** with the DyeMansion DM60

For the skin irritation 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 used parts dyed with the following mixtures have **not shown any skin irritation potential:**

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 skin irritation 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 skin irritation potential 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.

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FUTURE.**