

CERTIFICATE

MJF: PSS + DDC

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

Biological evaluation 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

**DYE
MANSION**

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 MJF (Multi Jet Fusion) parts were treated as follows:

- ✓ **Cleaning** with the DyeMansion Powershot C
- ✓ **PolyShot Surfacing** with the DyeMansion Powershot S
- ✓ **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)	HP 3D HR PA 12	HP Inc.	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.

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CERTIFICATE

MJF: VFS

DYE
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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

DyeMansion GmbH
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Germany

DATE OF ISSUE

December 5, 2020

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 MJF (Multi Jet Fusion) parts were treated as follows:

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

The following tested parts have **not shown any skin irritation potential:**

MATERIAL CLASS	MATERIAL NAME	SUPPLIER
Polyamide 12 (PA 12)	HP 3D HR PA 12	HP Inc.

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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CERTIFICATE

MJF: PSS + DDC

**DYE
MANSION**

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

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

DATE OF ISSUE

December 28, 2020

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 MJF (Multi Jet Fusion) parts were treated as follows:

- ✓ **Cleaning** with the DyeMansion Powershot C
- ✓ **PolyShot Surfacing** with the DyeMansion Powershot 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)	HP 3D HR PA 12	HP Inc.	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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