

**Sponsor**

DyeMansion GmbH
Robert-Koch-Str. 1
82152 Planegg-München, Germany

Testing Facility

FREY-TOX GmbH
Osteroda 38
04916 Herzberg, Germany

Test certificate

based on results of GLP study Lab. No. 04062

Mixed sample of:

DM Yellow R2, DM Red R3, DM Red R5, DM Red R6, DM Blue R4

Biological evaluation of medical devices

Test on extracts for *in vitro* cytotoxicity (ISO 10993-5)

Extract of the mixed sample DM Yellow R2, DM Red R3, DM Red R5, DM Red R6, DM Blue R4 is classified as **not cytotoxic** based on results obtained in accordance to ISO Guidelines 10993-5 and ISO 10993-12.

Detailed descriptions of utilized test and reference items, applied methods, test conditions, observations and obtained results as well as responsibilities for the study are presented in the final report of GLP study Lab. No. 04062.

Herzberg, 21-Nov-2018

Study Director

Dipl.-Biol. Anja Vaeth

Managing Director

Dr. Christiane Freytag

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DyeMansion GmbH
Robert-Koch-Str. 1
82152 Planegg-München, Germany

Testing Facility

FREY-TOX GmbH
Osteroda 38
04916 Herzberg, Germany

Test certificate

based on results of GLP study Lab. No. 04061

Mixed sample of:

DM Yellow N1, DM Blue N1, DM Blue N3, DM Blue N5, DM Blue N6

Biological evaluation of medical devices

Test on extracts for *in vitro* cytotoxicity (ISO 10993-5)

Extract of the mixed sample DM Yellow N1, DM Blue N1, DM Blue N3, DM Blue N5, DM Blue N6 is classified as **not cytotoxic** based on results obtained in accordance to ISO Guidelines 10993-5 and ISO 10993-12.

Detailed descriptions of utilized test and reference items, applied methods, test conditions, observations and obtained results as well as responsibilities for the study are presented in the final report of GLP study Lab. No. 04061.

Herzberg, 21-Nov-2018

Study Director
Dipl.-Biol. Anja Vaeth

Managing Director
Dr. Christiane Freytag

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Robert-Koch-Str. 1
82152 Planegg-München, Germany

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FREY-TOX GmbH
Osteroda 38
04916 Herzberg, Germany

Test certificate

based on results of GLP study Lab. No. 04059

Mixed sample of:

DM Brown N1, DM Brown N2, DM Red N1, DM Red N2, DM Red N4

Biological evaluation of medical devices

Test on extracts for *in vitro* cytotoxicity (ISO 10993-5)

Extract of the mixed sample DM Brown N1, DM Brown N2, DM Red N1, DM Red N2, DM Red N4 is classified as **not cytotoxic** based on results obtained in accordance to ISO Guidelines 10993-5 and ISO 10993-12.

Detailed descriptions of utilized test and reference items, applied methods, test conditions, observations and obtained results as well as responsibilities for the study are presented in the final report of GLP study Lab. No. 04059.

Herzberg, 21-Nov-2018

Study Director

Dipl.-Biol. Anja Vaeth

Managing Director

Dr. Christiane Freytag

**Sponsor**

DyeMansion GmbH
Robert-Koch-Str. 1
82152 Planegg-München, Germany

Testing Facility

FREY-TOX GmbH
Osteroda 38
04916 Herzberg, Germany

Test certificate

based on results of GLP study Lab. No. 04087

DM Blue N7

Biological evaluation of medical devices
Test on extracts for *in vitro* cytotoxicity (ISO 10993-5)

Extract of the sample DM Blue N7 is classified as **not cytotoxic** based on results obtained in accordance to ISO Guidelines 10993-5 and ISO 10993-12.

Detailed descriptions of utilized test item and reference items, applied methods, test conditions, observations and obtained results as well as responsibilities for the study are presented in the final report of GLP study Lab. No. 04087.

Herzberg, 25-Jan-2019

Study Director
Dipl.-Biol. Anja Vaeth

Managing Director
Dr. Christiane Freytag

**Sponsor**

DyeMansion GmbH
Robert-Koch-Str. 1
82152 Planegg-München, Germany

Testing Facility

FREY-TOX GmbH
Osteroda 38
04916 Herzberg, Germany

Test certificate

based on results of GLP study Lab. No. 04088

DM Yellow N3

Biological evaluation of medical devices
Test on extracts for *in vitro* cytotoxicity (ISO 10993-5)

Extract of the sample DM Yellow N3 is classified as **not cytotoxic** based on results obtained in accordance to ISO Guidelines 10993-5 and ISO 10993-12.

Detailed descriptions of utilized test item and reference items, applied methods, test conditions, observations and obtained results as well as responsibilities for the study are presented in the final report of GLP study Lab. No. 04088.

Herzberg, 25-Jan-2019

Study Director
Dipl.-Biol. Anja Vaeth

Managing Director
Dr. Christiane Freytag

**Sponsor**

DyeMansion GmbH
Robert-Koch-Str. 1
82152 Planegg-München, Germany

Testing Facility

FREY-TOX GmbH
Osteroda 38
04916 Herzberg, Germany

Test certificate

based on results of GLP study Lab. No. 04089

DM Red N7

Biological evaluation of medical devices
Test on extracts for *in vitro* cytotoxicity (ISO 10993-5)

Extract of the sample DM Red N7 is classified as **not cytotoxic** based on results obtained in accordance to ISO Guidelines 10993-5 and ISO 10993-12.

Detailed descriptions of utilized test item and reference items, applied methods, test conditions, observations and obtained results as well as responsibilities for the study are presented in the final report of GLP study Lab. No. 04089.

Herzberg, 25-Jan-2019

Study Director
Dipl.-Biol. Anja Vaeth

Managing Director
Dr. Christiane Freytag

**Sponsor**

DyeMansion GmbH
Robert-Koch-Str. 1
82152 Planegg-München, Germany

Testing Facility

FREY-TOX GmbH
Osteroda 38
04916 Herzberg, Germany

Test certificate

based on results of GLP study Lab. No. 04090

DM Grey N1

Biological evaluation of medical devices
Test on extracts for *in vitro* cytotoxicity (ISO 10993-5)

Extract of the sample DM Grey N1 is classified as **not cytotoxic** based on results obtained in accordance to ISO Guidelines 10993-5 and ISO 10993-12.

Detailed descriptions of utilized test item and reference items, applied methods, test conditions, observations and obtained results as well as responsibilities for the study are presented in the final report of GLP study Lab. No. 04090.

Herzberg, 25-Jan-2019

Study Director
Dipl.-Biol. Anja Vaeth

Managing Director
Dr. Christiane Freytag

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Osteroda 38
04916 Herzberg, Germany

Test certificate

based on results of GLP study Lab. No. 04091

DM Black N1 EOS**Biological evaluation of medical devices****Test on extracts for *in vitro* cytotoxicity (ISO 10993-5)**

Extract of the sample DM Black N1 EOS is classified as **not cytotoxic** based on results obtained in accordance to ISO Guidelines 10993-5 and ISO 10993-12.

Detailed descriptions of utilized test item and reference items, applied methods, test conditions, observations and obtained results as well as responsibilities for the study are presented in the final report of GLP study Lab. No. 04091.

Herzberg, 25-Jan-2019

Study Director

Dipl.-Biol. Anja Vaeth

Managing Director

Dr. Christiane Freytag