



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. 04104

**Mixed sample of the 5 test items: DM Yellow N3, DM Brown N2, DM Red N4,
DM Blue N3, DM Black N1 EOS**

***In vitro* skin irritation test on medical device extracts using
reconstructed human epidermis (RhE) EpiDerm™**

Based on the results of the *in vitro* investigation according to ISO protocol ISO/TC 194 WG 8 Irritation and Skin Sensitization Protocol for a Round Robin Study (10-Mar-2016) as well as ISO guideline 10993-12, the conclusion can be summarized, that **no skin irritation potential** has been shown for the extracts from mixed samples consisting of the 5 test items DM Yellow N3, DM Brown N2, DM Red N4, DM Blue N3 and DM Black N1 EOS each.

Detailed descriptions of used test items and reference materials, applied methods, test conditions, observations, measurements and results as well as responsibilities are presented in the Final Report of GLP study Lab. No. 04104.

Herzberg, 12-Apr-2019

A handwritten signature in blue ink, appearing to read 'Anja Vaeth', written over a horizontal line.

Study Director
Dipl.-Biol. Anja Vaeth

A handwritten signature in blue ink, appearing to read 'Dr. Christiane Freytag', written over a horizontal line.

Managing Director
Dr. Christiane Freytag



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based on results of GLP study Lab. No. 04105

Mixed sample of the 4 test items: DM Yellow R2, DM Red R5, DM Red R6, DM Blue R4

***In vitro* skin irritation test on medical device extracts using
reconstructed human epidermis (RhE) EpiDerm™**

Based on the results of the *in vitro* investigation according to ISO protocol ISO/TC 194 WG 8 Irritation and Skin Sensitization Protocol for a Round Robin Study (10-Mar-2016) as well as ISO guideline 10993-12, the conclusion can be summarized, that **no skin irritation potential** has been shown for the extracts from mixed samples consisting of the 4 test items DM Yellow R2, DM Red R5, DM Red R6 and DM Blue R4 each.

Detailed descriptions of used test items and reference materials, applied methods, test conditions, observations, measurements and results as well as responsibilities are presented in the Final Report of GLP study Lab. No. 04105.

Herzberg, 12-Apr-2019

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Study Director
Dipl.-Biol. Anja Vaeth

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Managing Director
Dr. Christiane Freytag



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based on results of GLP study Lab. No. 04106

Mixed sample of the 4 test items: DM Red N2, DM Blue N1, DM Blue N5, DM Blue N6

***In vitro* skin irritation test on medical device extracts using
reconstructed human epidermis (RhE) EpiDerm™**

Based on the results of the *in vitro* investigation according to ISO protocol ISO/TC 194 WG 8 Irritation and Skin Sensitization Protocol for a Round Robin Study (10-Mar-2016) as well as ISO guideline 10993-12, the conclusion can be summarized, that **no skin irritation potential** has been shown for the extracts from mixed samples consisting of the 4 test items DM Red N2, DM Blue N1, DM Blue N5 und DM Blue N6 each.

Detailed descriptions of used test items and reference materials, applied methods, test conditions, observations, measurements and results as well as responsibilities are presented in the Final Report of GLP study Lab. No. 04106.

Herzberg, 12-Apr-2019

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Study Director
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Managing Director
Dr. Christiane Freytag



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based on results of GLP study Lab. No. 04107

Mixed sample of the 4 test items: DM Red N1, DM Red N7, DM Blue N7, DM Grey N1

***In vitro* skin irritation test on medical device extracts using
reconstructed human epidermis (RhE) EpiDerm™**

Based on the results of the *in vitro* investigation according to ISO protocol ISO/TC 194 WG 8 Irritation and Skin Sensitization Protocol for a Round Robin Study (10-Mar-2016) as well as ISO guideline 10993-12, the conclusion can be summarized, that **no skin irritation potential** has been shown for the extracts from mixed samples consisting of the 4 test items DM Red N1, DM Red N7, DM Blue N7 and DM Grey N1 each.

Detailed descriptions of used test items and reference materials, applied methods, test conditions, observations, measurements and results as well as responsibilities are presented in the Final Report of GLP study Lab. No. 04107.

Herzberg, 12-Apr-2019

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Study Director
Dipl.-Biol. Anja Vaeth

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Managing Director
Dr. Christiane Freytag



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Test certificate

based on results of GLP study Lab. No. 04108

Mixed sample of the 3 test items: DM Yellow N1, DM Brown N1, DM Red R3

***In vitro* skin irritation test on medical device extracts using
reconstructed human epidermis (RhE) EpiDerm™**

Based on the results of the *in vitro* investigation according to ISO protocol ISO/TC 194 WG 8 Irritation and Skin Sensitization Protocol for a Round Robin Study (10-Mar-2016) as well as ISO guideline 10993-12, the conclusion can be summarized, that **no skin irritation potential** has been shown for the extracts from mixed samples consisting of the 3 test items DM Yellow N1, DM Brown N1 and DM Red R3 each.

Detailed descriptions of used test items and reference materials, applied methods, test conditions, observations, measurements and results as well as responsibilities are presented in the Final Report of GLP study Lab. No. 04108.

Herzberg, 12-Apr-2019

Study Director
Dipl.-Biol. Anja Vaeth

Managing Director
Dr. Christiane Freytag