Ortho Clinical Diagnostics

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

DECLARATION OF CONFORMITY

Manufacturer:

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester
New York 14626
USA

Authorized Representative:

Ortho-Clinical Diagnostics
50 – 100 Holmers Farm Way
High Wycombe
Buckinghamshire HP12 4DP
United Kingdom

Ortho-Clinical Diagnostics is declaring that the in vitro diagnostic medical devices below comply with the provisions of Directive 98/79/EC on *In Vitro* Diagnostic Medical Devices and the UK Medical Devices Regulations 2002 No: 618.

Product Name: VITROS Chemistry Products Calibrator Kit 20

Product Code: 680 1704

Classification: Non-Annex II

STANDARDS APPLIED:

- EN ISO 14971: 2009 Medical devices – Application of risk management to medical devices
- EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- EN 13640:2002 Stability testing of in vitro diagnostic reagents

Ortho Clinical Diagnostics

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

DECLARATION OF CONFORMITY *(continued)*

STANDARDS APPLIED ***(continued)***

- EN 13641:2002 Elimination or reduction of risk of infections related to in vitro diagnostic medical devices
- EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 1: Terms, definitions and general requirements
- EN ISO 18113-2:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 2: In vitro diagnostic reagents for professional use
- EN ISO 13485:2012 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
- EN ISO 15223-1:2012 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- ISO 17511:2003 In vitro diagnostic systems - Measurement of quantities in samples of biological origin - Metrological traceability of values assigned to calibrators and control materials.

Date of original CE-marking: 2004-10-18

Bryan A. Lisa
Worldwide Director, Regulatory Affairs
Raritan, NJ, USA

16 Sept. 2015
(year-month-day)

Ortho Clinical Diagnostics

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

DECLARATION OF CONFORMITY

Manufacturer:

Ortho-Clinical Diagnostics, Inc.
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Authorized Representative:

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50 – 100 Holmers Farm Way
High Wycombe
Buckinghamshire HP12 4DP
United Kingdom

Ortho-Clinical Diagnostics is declaring that the in vitro diagnostic medical devices below comply with the provisions of Directive 98/79/EC on *In Vitro* Diagnostic Medical Devices and the UK Medical Devices Regulations 2002 No: 618.

Product Name: VITROS Chemistry Products hsCRP Performance Verifier I, II and III

Product Code: 680 1742, 680 1888 and 680 2049

Classification: Non-Annex II

STANDARDS APPLIED:

- EN ISO 14971: 2009 Medical devices – Application of risk management to medical devices
- EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- EN 13640:2002 Stability testing of in vitro diagnostic reagents

Ortho Clinical Diagnostics

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

DECLARATION OF CONFORMITY *(continued)*

STANDARDS APPLIED *(continued)*

- EN 13641:2002 Elimination or reduction of risk of infections related to in vitro diagnostic medical devices
- EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 1: Terms, definitions and general requirements
- EN ISO 18113-2:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 2: In vitro diagnostic reagents for professional use
- EN ISO 13485:2012 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
- EN ISO 15223-1:2012 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- ISO 17511:2003 In vitro diagnostic systems - Measurement of quantities in samples of biological origin - Metrological traceability of values assigned to calibrators and control materials.

Date of original CE-marking: 2004-09-24

Bryan A. Lisa
Worldwide Director, Regulatory Affairs
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16 Sept. 2015
(year-month-day)

Ortho Clinical Diagnostics

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

DECLARATION OF CONFORMITY

Manufacturer:

Ortho-Clinical Diagnostics, Inc.
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50 – 100 Holmers Farm Way
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Buckinghamshire HP12 4DP
United Kingdom

Ortho-Clinical Diagnostics is declaring that the in vitro diagnostic medical devices below comply with the provisions of Directive 98/79/EC on *In Vitro* Diagnostic Medical Devices and the UK Medical Devices Regulations 2002 No: 618.

Product Name: VITROS Chemistry Products Protein Performance Verifiers I, II and III

Product Code: 680 1744, 680 1745 and 680 1768

Classification: Non-Annex II

STANDARDS APPLIED:

- EN ISO 14971: 2009 Medical devices – Application of risk management to medical devices
- EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- EN 13640:2002 Stability testing of in vitro diagnostic reagents

Ortho Clinical Diagnostics

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

DECLARATION OF CONFORMITY *(continued)*

STANDARDS APPLIED ***(continued)***

- EN 13641:2002 Elimination or reduction of risk of infections related to in vitro diagnostic medical devices
- EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 1: Terms, definitions and general requirements
- EN ISO 18113-2:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 2: In vitro diagnostic reagents for professional use
- EN ISO 13485:2012 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
- EN ISO 15223-1:2012 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- ISO 17511:2003 In vitro diagnostic systems - Measurement of quantities in samples of biological origin - Metrological traceability of values assigned to calibrators and control materials.

Date of original CE-marking: 2004-10-18

Bryan A. Lisa
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Raritan, NJ, USA

2015 Sept. 16
(year-month-day)

Ortho Clinical Diagnostics

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Manufacturer:

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Rochester
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United Kingdom

Ortho-Clinical Diagnostics is declaring that the in vitro diagnostic medical devices below comply with the provisions of Directive 98/79/EC on *In Vitro* Diagnostic Medical Devices and the UK Medical Devices Regulations 2002 No: 618.

Product Name: VITROS Chemistry Products HbA1c Reagent Kit

Product Code: 684 2905

Classification: Non-Annex II

STANDARDS APPLIED:

- EN ISO 14971:2012 Medical Devices – Application of Risk Management to Medical Devices (European Union)
- EN ISO 14971:2007 Medical Devices – Application of Risk Management to Medical Devices
- EN 13640:2002 Stability testing of in vitro diagnostic reagents

DECLARATION OF CONFORMITY *(continued)*

STANDARDS APPLIED *(continued)*

- EN 13641:2002 Elimination or reduction of risk of infections related to in vitro diagnostic medical devices
- EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 1: Terms, definitions and general requirements
- EN ISO 18113-2:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 2: In vitro diagnostic reagents for professional use
- EN ISO 13485:2012 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
- EN ISO 15223-1:2012 Medical devices -- Symbols to be used with medical device labels, labeling and information to be supplied -- Part 1: General requirements
- EN ISO 17511:2003 In vitro diagnostic systems - Measurement of quantities in samples of biological origin - Metrological traceability of values assigned to calibrators and control materials.

Date of original CE-marking: 2014-09-17

Bryan A. Lisa
Director, Worldwide Regulatory Affairs

17 Sept. 2014
Date

Ortho Clinical Diagnostics

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

DECLARATION OF CONFORMITY

Manufacturer:

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Buckinghamshire HP12 4DP
United Kingdom

Ortho-Clinical Diagnostics is declaring that the in vitro diagnostic medical devices below comply with the provisions of Directive 98/79/EC on *In Vitro* Diagnostic Medical Devices and the UK Medical Devices Regulations 2002 No: 618.

Product Name: VITROS Chemistry Products Calibrator Kit 28

Product Code: 680 2323

Classification: Non-Annex II

STANDARDS APPLIED:

- EN ISO 14971: 2009 Medical devices – Application of risk management to medical devices
- EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- EN 13640:2002 Stability testing of in vitro diagnostic reagents

Ortho Clinical Diagnostics

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

DECLARATION OF CONFORMITY *(continued)*

STANDARDS APPLIED ***(continued)***

- EN 13641:2002 Elimination or reduction of risk of infections related to in vitro diagnostic medical devices
- EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 1: Terms, definitions and general requirements
- EN ISO 18113-2:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 2: In vitro diagnostic reagents for professional use
- EN ISO 13485:2012 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
- EN ISO 15223-1:2012 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- ISO 17511:2003 In vitro diagnostic systems - Measurement of quantities in samples of biological origin - Metrological traceability of values assigned to calibrators and control materials.

Date of original CE-marking: 2005-12-21

Bryan A. Lisa
Worldwide Director, Regulatory Affairs
Raritan, NJ, USA

2015 Sept. 16
(year-month-day)

Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY

Manufacturer:

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100 Indigo Creek Drive
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Ortho-Clinical Diagnostics
Felindre Meadows
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United Kingdom

Ortho-Clinical Diagnostics is declaring that the in vitro diagnostic medical devices below comply with the provisions of Directive 98/79/EC on *In Vitro* Diagnostic Medical Devices and the UK Medical Devices Regulations 2002 No: 618.

Product Name: VITROS Chemistry Products %A1c Performance Verifiers I and II

Product Code: 680 1750 and 680 1751

Classification: Non-Annex II

Conformity Assessment Route: Annex III

STANDARDS APPLIED:

- EN ISO 14971: 2009 Medical devices – Application of risk management to medical devices
- EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- EN 13640:2002 Stability testing of in vitro diagnostic reagents
- EN 13641:2002 Elimination or reduction of risk of infections related to in vitro diagnostic medical devices
- EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 1: Terms, definitions and general requirements
- EN ISO 18113-2:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 2: In vitro diagnostic reagents for professional use

Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY *(continued)*

STANDARDS APPLIED *(continued)*

- EN ISO 13485:2012 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
- EN ISO 15223-1:2012 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- ISO 17511:2003 In vitro diagnostic systems - Measurement of quantities in samples of biological origin - Metrological traceability of values assigned to calibrators and control materials.

Date of original CE-marking: 2004-09-24

Bryan A. Lisa
Raritan, New Jersey, USA
Director, Worldwide Regulatory Affairs

2015 - Dec - 8
Date: (year-month-day)

Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY

Manufacturer:

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United Kingdom

Ortho-Clinical Diagnostics is declaring that the in vitro diagnostic medical devices below comply with the provisions of Directive 98/79/EC on *In Vitro* Diagnostic Medical Devices and the UK Medical Devices Regulations 2002 No: 618.

Product Name: VITROS Chemistry Products Calibrator Kit 18

Product Code: 680 1702

Classification: Non-Annex II

Conformity Assessment Route: Annex III

STANDARDS APPLIED:

- EN ISO 14971: 2009 Medical devices – Application of risk management to medical devices
- EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- EN 13640:2002 Stability testing of in vitro diagnostic reagents
- EN 13641:2002 Elimination or reduction of risk of infections related to in vitro diagnostic medical devices
- EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 1: Terms, definitions and general requirements
- EN ISO 18113-2:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 2: In vitro diagnostic reagents for professional use

Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY *(continued)*

STANDARDS APPLIED ***(continued)***

- EN ISO 13485:2012 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
- EN ISO 15223-1:2012 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- ISO 17511:2003 In vitro diagnostic systems - Measurement of quantities in samples of biological origin - Metrological traceability of values assigned to calibrators and control materials.

Date of original CE-marking: 2004-09-24

Bryan A. Lisa
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Raritan, New Jersey, USA

2015-Dec-8
Date: (year-month-day)

Ortho Clinical Diagnostics

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Buckinghamshire HP12 4DP
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Ortho-Clinical Diagnostics is declaring that the in vitro diagnostic medical devices below comply with the provisions of Directive 98/79/EC on *In Vitro* Diagnostic Medical Devices and the UK Medical Devices Regulations 2002 No: 618.

Product Name: VITROS Chemistry Products ASO Reagent

Product Code: 680 2218

Classification: Non-Annex II

STANDARDS APPLIED:

- EN ISO 14971: 2009 Medical devices – Application of risk management to medical devices
- EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- EN 13640:2002 Stability testing of in vitro diagnostic reagents

Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY *(continued)*

STANDARDS APPLIED ***(continued)***

- EN 13641:2002 Elimination or reduction of risk of infections related to in vitro diagnostic medical devices
- EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 1: Terms, definitions and general requirements
- EN ISO 18113-2:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 2: In vitro diagnostic reagents for professional use
- EN ISO 13485:2012 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
- EN ISO 15223-1:2012 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- ISO 17511:2003 In vitro diagnostic systems - Measurement of quantities in samples of biological origin - Metrological traceability of values assigned to calibrators and control materials.

Date of original CE-marking: 2005-12-21

Bryan A. Lisa
Director, Worldwide Regulatory Affairs

2014-Nov-20
(year-month-day)

Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY

Manufacturer:

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High Wycombe
Buckinghamshire HP12 4DP
United Kingdom

Ortho-Clinical Diagnostics is declaring that the in vitro diagnostic medical devices below comply with the provisions of Directive 98/79/EC on *In Vitro* Diagnostic Medical Devices and the UK Medical Devices Regulations 2002 No: 618.

Product Name: VITROS Chemistry Products ASO/RF Performance Verifiers I and II

Product Code: 680 2411 and 680 2412

Classification: Non-Annex II

STANDARDS APPLIED:

- EN ISO 14971: 2009 Medical devices – Application of risk management to medical devices
- EN ISO 14971: 2012 Medical devices – Application of risk management to medical devices
- EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- EN 13640:2002 Stability testing of in vitro diagnostic reagents

Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY *(continued)*

STANDARDS APPLIED ***(continued)***

- EN 13641:2002 Elimination or reduction of risk of infections related to in vitro diagnostic medical devices
- EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 1: Terms, definitions and general requirements
- EN ISO 18113-2:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 2: In vitro diagnostic reagents for professional use
- EN ISO 13485:2012 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
- EN ISO 15223-1:2012 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- ISO 17511:2003 In vitro diagnostic systems - Measurement of quantities in samples of biological origin - Metrological traceability of values assigned to calibrators and control materials.

Date of original CE-marking: 2005-12-21

2015 Aug. 19

Name: Bryan A. Lisa
Date: (year-month-day)
Place: Raritan, New Jersey, USA
Title: Director, Worldwide Regulatory Affairs

Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY

Manufacturer:

Ortho-Clinical Diagnostics, Inc.
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50 – 100 Holmers Farm Way
High Wycombe
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United Kingdom

Ortho-Clinical Diagnostics is declaring that the in vitro diagnostic medical devices below comply with the provisions of Directive 98/79/EC on *In Vitro* Diagnostic Medical Devices and the UK Medical Devices Regulations 2002 No: 618.

Product Name: VITROS Chemistry Products C3 Reagent

Product Code: 680 1735

Classification: Non-Annex II

STANDARDS APPLIED:

- EN ISO 14971: 2009 Medical devices – Application of risk management to medical devices
- EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- EN 13640:2002 Stability testing of in vitro diagnostic reagents

Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY *(continued)*

STANDARDS APPLIED *(continued)*

- EN 13641:2002 Elimination or reduction of risk of infections related to in vitro diagnostic medical devices
- EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 1: Terms, definitions and general requirements
- EN ISO 18113-2:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 2: In vitro diagnostic reagents for professional use
- EN ISO 13485:2012 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
- EN ISO 15223-1:2012 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- ISO 17511:2003 In vitro diagnostic systems - Measurement of quantities in samples of biological origin - Metrological traceability of values assigned to calibrators and control materials.

Date of original CE-marking: 2004-10-18

Bryan A. Lisa
Director, Worldwide Regulatory Affairs

2014-Nov-19
(year-month-day)

Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY

Manufacturer:

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Buckinghamshire HP12 4DP
United Kingdom

Ortho-Clinical Diagnostics is declaring that the in vitro diagnostic medical devices below comply with the provisions of Directive 98/79/EC on *In Vitro* Diagnostic Medical Devices and the UK Medical Devices Regulations 2002 No: 618.

Product Name: VITROS Chemistry Products C4 Reagent

Product Code: 680 1736

Classification: Non-Annex II

STANDARDS APPLIED:

- EN ISO 14971: 2009 Medical devices – Application of risk management to medical devices
- EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- EN 13640:2002 Stability testing of in vitro diagnostic reagents

DECLARATION OF CONFORMITY *(continued)*

STANDARDS APPLIED ***(continued)***

- EN 13641:2002 Elimination or reduction of risk of infections related to in vitro diagnostic medical devices
- EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 1: Terms, definitions and general requirements
- EN ISO 18113-2:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 2: In vitro diagnostic reagents for professional use
- EN ISO 13485:2012 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
- EN ISO 15223-1:2012 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- ISO 17511:2003 In vitro diagnostic systems - Measurement of quantities in samples of biological origin - Metrological traceability of values assigned to calibrators and control materials.

Date of original CE-marking: 2004-10-18

Bryan A. Lisa
Director, Worldwide Regulatory Affairs

2014-Nov-19
(year-month-day)

Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY

Manufacturer:

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Buckinghamshire HP12 4DP
United Kingdom

Ortho-Clinical Diagnostics is declaring that the in vitro diagnostic medical devices below comply with the provisions of Directive 98/79/EC on *In Vitro* Diagnostic Medical Devices and the UK Medical Devices Regulations 2002 No: 618.

Product Name: VITROS Chemistry Products Calibrator Kit 11

Product Code: 680 1696

Classification: Non-Annex II

STANDARDS APPLIED:

- EN ISO 14971: 2009 Medical devices – Application of risk management to medical devices
- EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- EN 13640:2002 Stability testing of in vitro diagnostic reagents

Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY *(continued)*

STANDARDS APPLIED *(continued)*

- EN 13641:2002 Elimination or reduction of risk of infections related to in vitro diagnostic medical devices
- EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 1: Terms, definitions and general requirements
- EN ISO 18113-2:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 2: In vitro diagnostic reagents for professional use
- EN ISO 13485:2012 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
- EN ISO 15223-1:2012 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- ISO 17511:2003 In vitro diagnostic systems - Measurement of quantities in samples of biological origin - Metrological traceability of values assigned to calibrators and control materials.

Date of original CE-marking: 2004-11-22

Bryan A. Lisa
Director, Worldwide Regulatory Affairs

2015 Jan. 7
(year-month-day)

Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY

Manufacturer:

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
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50 – 100 Holmers Farm Way
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Ortho-Clinical Diagnostics is declaring that the in vitro diagnostic medical devices below comply with the provisions of Directive 98/79/EC on *In Vitro* Diagnostic Medical Devices and the UK Medical Devices Regulations 2002 No: 618.

Product Name: VITROS Chemistry Products Calibrator Kit 12

Product Code: 680 1697

Classification: Non-Annex II

STANDARDS APPLIED:

- EN ISO 14971: 2009 Medical devices – Application of risk management to medical devices
- EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- EN 13640:2002 Stability testing of in vitro diagnostic reagents

Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY *(continued)*

STANDARDS APPLIED ***(continued)***

- EN 13641:2002 Elimination or reduction of risk of infections related to in vitro diagnostic medical devices
- EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 1: Terms, definitions and general requirements
- EN ISO 18113-2:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 2: In vitro diagnostic reagents for professional use
- EN ISO 13485:2012 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
- EN ISO 15223-1:2012 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- ISO 17511:2003 In vitro diagnostic systems - Measurement of quantities in samples of biological origin - Metrological traceability of values assigned to calibrators and control materials.

Date of original CE-marking: 2005-01-18

Bryan A. Lisa
Director, Worldwide Regulatory Affairs

2015 Jan 7
(year-month-day)

Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY

Manufacturer:

Ortho-Clinical Diagnostics, Inc.
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Authorized Representative:

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Felindre Meadows
Pencoed
Bridgend CF35 5PZ
United Kingdom

Ortho-Clinical Diagnostics is declaring that the in vitro diagnostic medical devices below comply with the provisions of Directive 98/79/EC on *In Vitro* Diagnostic Medical Devices and the UK Medical Devices Regulations 2002 No: 618.

Product Name: VITROS Chemistry Products Calibrator Kit 17

Product Code: 680 1701

Classification: Non-Annex II

Conformity Assessment Route: Annex III

STANDARDS APPLIED:

- EN ISO 14971: 2012 Medical devices – Application of risk management to medical devices
- EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- EN 13640:2002 Stability testing of in vitro diagnostic reagents
- EN 13641:2002 Elimination or reduction of risk of infections related to in vitro diagnostic medical devices
- EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 1: Terms, definitions and general requirements
- EN ISO 18113-2:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 2: In vitro diagnostic reagents for professional use

Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY *(continued)*

STANDARDS APPLIED ***(continued)***

- EN ISO 13485:2012 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
- EN ISO 15223-1:2012 Medical devices -- Symbols to be used with medical device labels, labeling and information to be supplied -- Part 1: General requirements
- ISO 17511:2003 In vitro diagnostic systems - Measurement of quantities in samples of biological origin - Metrological traceability of values assigned to calibrators and control materials.

Date of original CE-marking: 2004-09-24

Bryan A. Lisa
Raritan, New Jersey, USA
Director, Worldwide Regulatory Affairs

2015-Dec-8
Date: (year-month-day)

Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY

Manufacturer:

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
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New York 14626
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Authorized Representative:

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Bridgend CF35 5PZ
United Kingdom

Ortho-Clinical Diagnostics is declaring that the in vitro diagnostic medical devices below comply with the provisions of Directive 98/79/EC on *In Vitro* Diagnostic Medical Devices and the UK Medical Devices Regulations 2002 No: 618.

Product Name: VITROS Chemistry Products FS Calibrator 1

Product Code: 680 1873

Classification: Non-Annex II

Conformity Assessment Route: Annex III

STANDARDS APPLIED:

- EN ISO 14971: 2012 Medical devices – Application of risk management to medical devices
- EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- EN 13640:2002 Stability testing of in vitro diagnostic reagents
- EN 13641:2002 Elimination or reduction of risk of infections related to in vitro diagnostic medical devices
- EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 1: Terms, definitions and general requirements
- EN ISO 18113-2:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 2: In vitro diagnostic reagents for professional use

Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY *(continued)*

STANDARDS APPLIED ***(continued)***

- EN ISO 13485:2012 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
- EN ISO 15223-1:2012 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- ISO 17511:2003 In vitro diagnostic systems - Measurement of quantities in samples of biological origin - Metrological traceability of values assigned to calibrators and control materials.

Date of original CE-marking: 2004-09-24

Bryan A. Lisa
Raritan, NJ, USA
Worldwide Director, Regulatory Affairs

2015-Dec-8
Date: (year-month-day)

Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY

Manufacturer:

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Ortho-Clinical Diagnostics is declaring that the in vitro diagnostic medical devices below comply with the provisions of Directive 98/79/EC on *In Vitro* Diagnostic Medical Devices and the UK Medical Devices Regulations 2002 No: 618.

Product Name: VITROS Chemistry Products IgG Reagent

Product Code: 680 1733

Classification: Non-Annex II

STANDARDS APPLIED:

- EN ISO 14971: 2009 Medical devices – Application of risk management to medical devices
- EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- EN 13640:2002 Stability testing of in vitro diagnostic reagents

Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY *(continued)*

STANDARDS APPLIED *(continued)*

- EN 13641:2002 Elimination or reduction of risk of infections related to in vitro diagnostic medical devices
- EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 1: Terms, definitions and general requirements
- EN ISO 18113-2:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 2: In vitro diagnostic reagents for professional use
- EN ISO 13485:2012 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
- EN ISO 15223-1:2012 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- ISO 17511:2003 In vitro diagnostic systems - Measurement of quantities in samples of biological origin - Metrological traceability of values assigned to calibrators and control materials.

Date of original CE-marking: 2004-10-18

Bryan A. Lisa
Director, Worldwide Regulatory Affairs

2014-Nov-19
(year-month-day)

Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY

Manufacturer:

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester
New York 14626
USA

Authorized Representative:

Ortho-Clinical Diagnostics
50 – 100 Holmers Farm Way
High Wycombe
Buckinghamshire HP12 4DP
United Kingdom

Ortho-Clinical Diagnostics is declaring that the in vitro diagnostic medical devices below comply with the provisions of Directive 98/79/EC on *In Vitro* Diagnostic Medical Devices and the UK Medical Devices Regulations 2002 No: 618.

Product Name: VITROS Chemistry Products IgM Reagent

Product Code: 680 1734

Classification: Non-Annex II

STANDARDS APPLIED:

- EN ISO 14971: 2009 Medical devices – Application of risk management to medical devices
- EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- EN 13640:2002 Stability testing of in vitro diagnostic reagents

Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY *(continued)*

STANDARDS APPLIED ***(continued)***

- EN 13641:2002 Elimination or reduction of risk of infections related to in vitro diagnostic medical devices
- EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 1: Terms, definitions and general requirements
- EN ISO 18113-2:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 2: In vitro diagnostic reagents for professional use
- EN ISO 13485:2012 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
- EN ISO 15223-1:2012 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- ISO 17511:2003 In vitro diagnostic systems - Measurement of quantities in samples of biological origin - Metrological traceability of values assigned to calibrators and control materials.

Date of original CE-marking: 2004-10-18

Bryan A. Lisa
Director, Worldwide Regulatory Affairs

2014-Nov-19
(year-month-day)

Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY

Manufacturer:

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
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Authorized Representative:

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Buckinghamshire HP12 4DP
United Kingdom

Ortho-Clinical Diagnostics is declaring that the in vitro diagnostic medical devices below comply with the provisions of Directive 98/79/EC on *In Vitro* Diagnostic Medical Devices and the UK Medical Devices Regulations 2002 No: 618.

Product Name: VITROS Chemistry Products mALB Reagent

Product Code: 680 1740

Classification: Non-Annex II

STANDARDS APPLIED:

- EN ISO 14971: 2012 Medical devices – Application of risk management to medical devices
- EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- EN 13640:2002 Stability testing of in vitro diagnostic reagents

Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY *(continued)*

STANDARDS APPLIED ***(continued)***

- EN 13641:2002 Elimination or reduction of risk of infections related to in vitro diagnostic medical devices
- EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 1: Terms, definitions and general requirements
- EN ISO 18113-2:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 2: In vitro diagnostic reagents for professional use
- EN ISO 13485:2012 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
- EN ISO 15223-1:2012 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- ISO 17511:2003 In vitro diagnostic systems - Measurement of quantities in samples of biological origin - Metrological traceability of values assigned to calibrators and control materials.

Date of original CE-marking: 2004-10-18

Bryan A. Lisa
Director, Worldwide Regulatory Affairs

2014-Nov-19
(year-month-day)

Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY

Manufacturer:

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United Kingdom

Ortho-Clinical Diagnostics is declaring that the in vitro diagnostic medical devices below comply with the provisions of Directive 98/79/EC on *In Vitro* Diagnostic Medical Devices and the UK Medical Devices Regulations 2002 No: 618.

Product Name: VITROS Chemistry Products RF Reagent

Product Code: 680 1729

Classification: Non-Annex II

STANDARDS APPLIED:

- EN ISO 14971: 2009 Medical devices – Application of risk management to medical devices
- EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- EN 13640:2002 Stability testing of in vitro diagnostic reagents

Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY *(continued)*

STANDARDS APPLIED *(continued)*

- EN 13641:2002 Elimination or reduction of risk of infections related to in vitro diagnostic medical devices
- EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 1: Terms, definitions and general requirements
- EN ISO 18113-2:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 2: In vitro diagnostic reagents for professional use
- EN ISO 13485:2012 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
- EN ISO 15223-1:2012 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- ISO 17511:2003 In vitro diagnostic systems - Measurement of quantities in samples of biological origin - Metrological traceability of values assigned to calibrators and control materials.

Date of original CE-marking: 2004-09-24

Bryan A. Lisa
Director, Worldwide Regulatory Affairs

2014 - Nov - 19
(year-month-day)

Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY

Manufacturer:

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Authorized Representative:

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50 – 100 Holmers Farm Way
High Wycombe
Buckinghamshire HP12 4DP
United Kingdom

Ortho-Clinical Diagnostics is declaring that the in vitro diagnostic medical devices below comply with the provisions of Directive 98/79/EC on *In Vitro* Diagnostic Medical Devices and the UK Medical Devices Regulations 2002 No: 618.

Product Name: VITROS Chemistry Products TRFRN Reagent

Product Code: 680 1767

Classification: Non-Annex II

STANDARDS APPLIED:

- EN ISO 14971: 2009 Medical devices – Application of risk management to medical devices
- EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- EN 13640:2002 Stability testing of in vitro diagnostic reagents

Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY *(continued)*

STANDARDS APPLIED ***(continued)***

- EN 13641:2002 Elimination or reduction of risk of infections related to in vitro diagnostic medical devices
- EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 1: Terms, definitions and general requirements
- EN ISO 18113-2:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 2: In vitro diagnostic reagents for professional use
- EN ISO 13485:2012 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
- EN ISO 15223-1:2012 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- ISO 17511:2003 In vitro diagnostic systems - Measurement of quantities in samples of biological origin - Metrological traceability of values assigned to calibrators and control materials.

Date of original CE-marking: 2004-10-18

Bryan A. Lisa
Director, Worldwide Regulatory Affairs

2014-Nov. 20
(year-month-day)

Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY

Manufacturer:

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50 – 100 Holmers Farm Way
High Wycombe
Buckinghamshire HP12 4DP
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Ortho-Clinical Diagnostics is declaring that the in vitro diagnostic medical devices below comply with the provisions of Directive 98/79/EC on *In Vitro* Diagnostic Medical Devices and the UK Medical Devices Regulations 2002 No: 618.

Product Name: VITROS Chemistry Products VALP Reagent

Product Code: 680 1710

Classification: Non-Annex II

STANDARDS APPLIED:

- EN ISO 14971: 2009 Medical devices – Application of risk management to medical devices
- EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- EN 13640:2002 Stability testing of in vitro diagnostic reagents

Ortho Clinical Diagnostics

DECLARATION OF CONFORMITY *(continued)*

STANDARDS APPLIED ***(continued)***

- EN 13641:2002 Elimination or reduction of risk of infections related to in vitro diagnostic medical devices
- EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 1: Terms, definitions and general requirements
- EN ISO 18113-2:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 2: In vitro diagnostic reagents for professional use
- EN ISO 13485:2012 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
- EN ISO 15223-1:2012 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- ISO 17511:2003 In vitro diagnostic systems - Measurement of quantities in samples of biological origin - Metrological traceability of values assigned to calibrators and control materials.

Date of original CE-marking: 2005-02-17

Bryan A. Lisa
Director, Worldwide Regulatory Affairs

2014 - Nov - 19
(year-month-day)