LORNE LABORATORIES

DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION

Product name	Catalogue number
RPR Carbon kit	044150A 044500A

MANUFACTURER

Name	Lorne Laboratories
Address	Unit 1 Cutbush Park Industrial Estate Danehill Lower Earley Berks, RG6 4UT
Country	United Kingdom

MEANS OF CONFORMITY

I hereby declare that the products listed above comply with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

This declaration is valid from 17 May 2015.

Eddy Velthuis
Technical Director

LORNE LABORATORIES

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
ASO Latex kit	031100A

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 13 April 2016.

Eddy Velthuis
Technical Director

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LORNE LABORATORIES

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
CRP Latex kit	850100A

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
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Technical Director

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LORNE LABORATORIES

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
RF Latex kit	830100A

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 13 April 2016.

Eddy Velthuis
Technical Director

File No A12241;
ISO 13485:2003, ISO 9001:2008

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Declaration of Conformity

HL-7-0692DC DOI 2015/08 (1)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5250H	Manual D-Dimer	47346

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson Title: Managing Director

Signed: Date: 25 Aug 2015

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MACHEREY-NAGEL

EC DECLARATION OF CONFORMITY

according to Annex III of the IVD Directive 98/79/EC

EG Konformitätserklärung

gemäß Anhang III der IVD Richtlinie 98/79/EG

We hereby declare that the in vitro diagnostic medical device (IVD)

URYXXON® Relax
REF 930 88

GMDN Code: CT943 Instrument/analyser IVDs
EDMA IVD Classification: 21 05 Urine Analyser

is classified as ***all other IVD*** according to Annex II of the European directive 98/79/EC on in vitro diagnostic medical devices (IVDD)

and complies with the essential requirements (Annex I) of the IVD Directive 98/79/EC.

In addition, it meets the requirements according to the following directive

European directive 2011/65/EU on the restriction of the use of certain hazardous sub-stances in electrical and electronic equipment (RoHS 2)

Hiermit erklären wir, dass das In-vitro-Diagnostikum (IVD)

URYXXON® Relax
REF 930 88

GMDN Code: CT943 Instrumente/Analysatoren, IVD
EDMA IVD Klassifizierung: 21 05 Urin Analysegerät

gemäß Anhang II der Europäischen Richtlinie 98/79/EG über In-vitro-Diagnostika als ***sonstiges IVD*** klassifiziert ist

und die Grundlegenden Anforderungen (Anhang I) der IVD Richtlinie 98/79/EG erfüllt.

Darüberhinaus erfüllt es die Anforderungen gemäß der folgenden Richtlinie

Europäische Richtlinie 2011/65/EU zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten (RoHS 2)

applied harmonized standards

angewandte Harmonisierte Normen

DIN EN ISO 9001:2008
DIN EN ISO 13485:2012 + AC:2012
DIN EN ISO 14971:2012

DIN EN ISO 18113-1:2010
DIN EN ISO 18113-3:2010
DIN EN 13612:2002
DIN EN 980:2008

DIN EN ISO 15223-1:2013
DIN EN 62366:2008
DIN EN 62304:2006

DIN EN 61010-1:2010

DIN EN 61010-2-101:2003-09

DIN EN 61326-1:2013

Düren, 12 September 2016

Quality management representative (authorized representative)

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EC DECLARATION OF CONFORMITY

according to Annex III of the IVD Directive 98/79/EC

EG Konformitätserklärung

gemäß Anhang III der IVD Richtlinie 98/79/EG

We hereby declare that the in vitro diagnostic medical device (IVD)

URYXXON® 500
REF 930 080

GMDN Code: CT943 Instrument/analyser IVDs
EDMA IVD Classification: 21 05 Urine Analyser

is classified as ***all other IVD*** according to Annex II of the European directive 98/79/EC on in vitro diagnostic medical devices (IVDD)

and complies with the essential requirements (Annex I) of the IVD Directive 98/79/EC.

In addition, it meets the requirements according to the following directive

European directive 2011/65/EU on the restriction of the use of certain hazardous sub-stances in electrical and electronic equipment (RoHS 2)

Hiermit erklären wir, dass das In-vitro-Diagnostikum (IVD)

URYXXON® 500
REF 930 080

GMDN Code: CT943 Instrumente/Analysatoren, IVD
EDMA IVD Klassifizierung: 21 05 Urin Analysegerät

gemäß Anhang II der Europäischen Richtlinie 98/79/EG über In-vitro-Diagnostika als ***sonstiges IVD*** klassifiziert ist

und die Grundlegenden Anforderungen (Anhang I) der IVD Richtlinie 98/79/EG erfüllt.

Darüberhinaus erfüllt es die Anforderungen gemäß der folgenden Richtlinie

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applied harmonized standards

angewandte Harmonisierte Normen

DIN EN ISO 9001:2008
DIN EN ISO 13485:2012 + AC:2012
DIN EN ISO 14971:2012

DIN EN ISO 18113-1:2010
DIN EN ISO 18113-3:2010
DIN EN 13612:2002
DIN EN 980:2008

DIN EN ISO 15223-1:2013
DIN EN 62366:2008
DIN EN 62304:2006

DIN EN 61010-1:2010

DIN EN 61010-2-101:2003-09

DIN EN 61326-1:2013

Düren, 12 September 2016

ppa.

Quality-management representative (authorized representative)

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EC Declaration of Conformity

EC Declaration of Conformity for In-vitro Diagnostic Products

The procedure for EC declaration of conformity was established on the basis of a full quality assurance system according to EN ISO 9001:2008 and EN ISO 13485:2012+AC:2012 according to the IVD directive 98/79/EC Annex IV, except chapters 4 and 6.

CE

We

Name of manufacturer	MACHEREY-NAGEL GmbH & Co. KG
Address:	MACHEREY-NAGEL GmbH & Co. KG Neumann-Neander-Strasse 6-8 D - 52355 Dueren Germany

confirm that the following test strips for professional use

Name of product	**Reference numbers**
Medi-Test Glucose PN	93017; 930965
Medi-Test Glucose	93001; 93024
Medi-Test Glucose 3	93003; 93026
Medi-Test Glucose/Keton	93020; 93025
Medi-Test Protein 2	93004; 93027
Medi-Test Keton	93005; 93028
Medi-Test Nitrit	93006; 93029
Medi-Test Combi 2	93015; 93037
Medi-Test Urbi	93012
Medi-Test Combi 3	93050
Medi-Test Combi 3A	93007; 93030
Medi-Test Combi 5	93009; 93032
Medi-Test Combi 5N	93035; 93036
Medi-Test Combi 5S	93055
Medi-Test Combi 6	93018; 93078
Medi-Test Combi 6A	93013; 93034
Medi-Test Combi 7	93010; 93022
Medi-Test Combi 7L	93031
Medi-Test Combi 8L	93021
Medi-Test Combi 9	93011; 93023
Medi-Test Combi 10	93056
Medi-Test Combi 10L	93058; 93079
Medi-Test Combi 10 SGL	93067; 93077
Medi-Test URYXXON Stick 10	93068; 930872
Medi-Test Combi 11	93060; 930871
Medi-Test Mikroalbumin	930874

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