SIEMENS

Declaration of Conformity

LEGAL MANUFACTURER:	**Siemens Healthcare Diagnostics Inc. Tarrytown, New York 10591-5097 USA**
PLACE OF MANUFACTURE:	**Vitrex Medical A/S Vasekaer 6-8 2730 Herlev. Denmark**
PRODUCT:	**Glass and Plastic Blood Collection Capillaries**
PRODUCT CATEGORY:	**See attachment 1**
CLASSIFICATION:	**Self Declaration**
CONFORMITY ASSESSMENT ROUTE:	**ANNEX III Applied**
STANDARDS APPLIED:	**ENISO14971:2001 - Application of risk management to Medical Devices EN375:2001- Information supplied by the manufacturer with In Vitro Diagnostic reagents for professional use. EN980:2003 - Graphical symbols for use in the labeling of Medical Devices. ENISO13485:2003 – Quality System for Medical Devices EN591:2001 - Instructions for Use for in Vitro Diagnostic Instruments for Professional Use EN1658:1997 - Requirements for marking IVD Instruments**
DOCUMENT MANAGEMENT SYSTEM No:	**43-64-02**
REV:	**4.0**

Siemens Healthcare Diagnostics Inc.
Norwood, Massachusetts, USA

16/Feb/2009

Noor Malki **Date**
Sr. Manager – Regulatory Affairs - POC

SIEMENS

Declaration of Conformity

We herewith declare that the above-mentioned product(s) meet the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices. The Manufacturer retains all supporting documentation.

		Attachment 1
REF (BAN)	**Product Code**	**Description**
05614986	108758	Blood Collection Capillaries M 'Cap 100 ul 500 Pack
08851318	471836	Blood Collection Capillaries for Ph/Blood Gas
01198961	473193	Blood Collection Capillaries Multicap 50 X 140 ul
06493996	473646	Blood Collection Capillaries Multicap
07162853	473763	Blood Collection Capillaries Multicap 50 X 175 ul Pack
01519512	473764	Blood Collection Capillaries Multicap
00855578	473823	Blood Collection Capillaries Multicap 100 X 60 ul Kit
04996974	478600	Blood Collection Capillary Tubes 100 ul
07938479	478604	Blood Collection Capillary Tubes 140 ul
07817051	478608	Blood Collection Capillary Tubes 140 ul
05974729	673394	Blood Collection Capillaries Multicap 100 ul (Pack OF 50)
00335434	00335434	Plastic Blood Capillaries Multicap 50 X 100 ul
05656514	05656514	Plastic Blood Capillaries Multicap 500 X 100 ul
04549544	04549544	Plastic Blood Capillaries Multicap-S
00325811	00325811	Plastic Blood Capillaries Multicap-S
06440221	06440221	Plastic Blood Capillaries Multicap 50 X 175 ul
02043295	02043295	Plastic Blood Capillaries Multicap 500 X 175 ul
08685906	478527	Caps
01687040	478601	Caps
01558100	478605	Caps
04019456	478606	Fleas
09851273	478647	Adapters
		End of List

Siemens Healthcare Diagnostics Inc. is the current legal manufacturer of all diagnostics products previously manufactured by Siemens Medical Solutions Diagnostics. During a transition period to update product labeling and customer documentation to indicate Siemens Healthcare Diagnostics Inc. as the legal manufacturer, products may be identified and labeled as either Siemens Healthcare Diagnostics Inc. or Siemens Medical Solutions Diagnostics.

This Declaration of Conformity is applicable for either Siemens Healthcare Diagnostics Inc., or Siemens Medical Solutions Diagnostics labeled product.

Siemens Healthcare Diagnostics Inc.
Norwood, Massachusetts, USA

16/Feb/2009

Noor Malki **Date**
Sr. Manager – Regulatory Affairs - POC

SIEMENS

Declaration of Conformity

LEGAL MANUFACTURER:	**Siemens Healthcare Diagnostics Inc. Tarrytown, New York 10591-5097 USA**
PLACE OF MANUFACTURE:	**Smiths Medical 10 Bowman Drive Keene, NH 03431-0724 U.S.A.**
PRODUCT:	**Rapidlyte Syringe**
PRODUCT CATEGORY:	**See attachment 1**
CLASSIFICATION:	**Self Declaration**
CONFORMITY ASSESSMENT ROUTE:	**ANNEX III Applied**
STANDARDS APPLIED:	**ENISO13485:2003 – Quality System for Medical Devices**
DOCUMENT MANAGEMENT SYSTEM No:	**43-53-02 A**
REV:	**5.0**

Siemens Healthcare Diagnostics Inc.
Norwood, Massachusetts, USA

JUNE/9/2010

Noor Malki **Date**
Director – Regulatory Affairs - POC

SIEMENS

Declaration of Conformity

We herewith declare that the above-mentioned product(s) meet the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices. The Manufacturer retains all supporting documentation.

		Attachment 1
REF (BAN)	**Product Code**	**Description**
08679280	08679280	Rapidlyte 1 mL syringe
04180028	04180028	Rapidlyte 3 mL syringe
05150149	05150149	Rapidlyte 3 mL syringe
06194484	06194484	Rapidlyte 3 mL syringe
08784181	08784181	Rapidlyte 1 mL syringe
02932901	02932901	Rapidlyte 1 mL syringe
07416421	07416421	Rapidlyte 1 mL syringe
04909133	04909133	Rapidlyte 3 mL syringe
00355281	00355281	Rapidlyte 3 mL syringe
06407844	06407844	Rapidlyte 3 mL syringe
		End of List

Siemens Healthcare Diagnostics Inc. is the current legal manufacturer of all diagnostics products previously manufactured by Siemens Medical Solutions Diagnostics. During a transition period to update product labeling and customer documentation to indicate Siemens Healthcare Diagnostics Inc. as the legal manufacturer, products may be identified and labeled as either Siemens Healthcare Diagnostics Inc. or Siemens Medical Solutions Diagnostics.

This Declaration of Conformity is applicable for either Siemens Healthcare Diagnostics Inc., or Siemens Medical Solutions Diagnostics labeled product.

Siemens Healthcare Diagnostics Inc.
Norwood, Massachusetts, USA

JUNE/9/2010

Noor Malki **Date**
Director – Regulatory Affairs - POC

SIEMENS

Declaration of Conformity

LEGAL MANUFACTURER:	**Siemens Healthcare Diagnostics, Inc. 511 Benedict Avenue Tarrytown, New York 10591-5097 USA**
PLACE OF MANUFACTURE:	**Siemens Healthcare Diagnostics Manufacturing Limited Northern Road, Chilton Industrial Estate Sudbury, Suffolk CO10 2XQ UK**
PRODUCT:	**RAPIDPoint 500 Instruments, and Consumables**
PRODUCT CATEGORY:	**See Attachment 1**
CLASSIFICATION:	**Self Declaration**
CONFORMITY ASSESSMENT ROUTE:	**ANNEX III Applied**
STANDARDS APPLIED:	**ENISO14971:2009 - Application of risk management to Medical Devices EN375:2001- Information supplied by the manufacturer with In Vitro Diagnostic reagents for professional use. EN ISO13485:2003 – Quality System for Medical Devices EN ISO17511:2003 - In Vitro Diagnostic Medical Devices – Measurement of quantities in biological samples – metrological traceability of values assigned to calibrators and control materials ISO 15223– 1: 2007- Symbols to be used with medical device labels, labeling, and information to be supplied— Part 1: General requirements ISO 15223–2: 2010- Symbols to be used with medical device labels, labeling, and information to be supplied— Part 2: Symbol development, selection and validation EN 13612:2002 - Performance evaluation of in vitro diagnostics medical devices IEC 62366:2008 – Medical Devices – Application of usability engineering to medical devices IEC 61010-1:2001 - Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 1: General requirements. EN 61010-1:2001 Safety Requirements for electrical equipment for measurement, control and laboratory use. Part 1 General requirements IEC/EN 61010- 2 - 081:2001 (1st Edition), amendment 1-2003 - Safety requirements for electrical equipment for measurement control and laboratory use. IEC/EN 61010- 2 - 101:2002 – Safety requirements for electrical equipment for measurement control and laboratory use.**

Siemens Healthcare Diagnostics, Inc.
Norwood, Massachusetts, USA

Susan Tibedo 20 Feb 2015

Susan Tibedo **Date**
Sr. Manager, Regulatory Affairs – POC

SIEMENS

Declaration of Conformity

STANDARDS APPLIED:

EN 61010- 2 – 081/A1:2003 - Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic analytical equipment for analysis and other purposes.
EN 61010- 2 - 101:2002 - Safety requirements for electrical equipment for measurement, control and laboratory use.
UL 61010-1:2008 - Safety Requirements for Electrical Equipment for Measurement, control and Laboratory Use - PART 1: General Requirements
CAN/CSA C22.2 No. 61010-1-04, Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use - Part 1: General Requirements
CAN/CSA C22.2 No. 61010-2-081:2004, Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 2-081
CAN/CSA C22.2 No. 61010-2-101:2004 Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use - Part 2-101: Particular Requirements for In Vitro Diagnostic (IVD) Medical Equipment
EN 60825-1:2007 – Safety of Laser Products
EN 60601-1-2:2007 - Electromagnetic emissions and immunity requirements for medical electrical equipment – Group 1 Equipment, Class B for non-life supporting equipment.
IEC 60601-1-2 Ed. 2.1- Electromagnetic emissions and immunity requirements for medical electrical equipment – Group 1 Equipment, Class B for non-life supporting equipment.

Siemens Healthcare Diagnostics, Inc.
Norwood, Massachusetts, USA

Susan Tibedo 26 Feb 2015

Susan Tibedo **Date**
Sr. Manager, Regulatory Affairs – POC

SIEMENS

Declaration of Conformity

We herewith declare that the above-mentioned product(s) meet the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices. The Manufacturer retains all supporting documentation.

Attachment 1			
SMN	**REF (BAN)**	**Product Code**	**Description**
10697306	10697306	10697306	RP500 BLOOD GAS ANALYSER ROW
10323175	05768789	130520	Rapidpoint 405 Measurement Cartridge BG-CO-OX 750
10327073	07846760	130521	Rapidpoint 405 Measurement Cartridge BG-CO-OX 400
10310469	04913211	130522	Rapidpoint 405 Measurement Cartridge Full + CO-OX 750
10313971	00724090	130523	Rapidpoint 405 Measurement Cartridge Full + CO-OX 400
10310310	01171974	118677	Wash Waste Cartridge Package (3)
10341179	09734609	118678	Wash Waste Cartridge Package
10329097	8930536	129672	Wash Waste Cartridge Package (4)
10310323	05293926	120241	AQC Cartridge Kit
10283221	06535606	10283221	Rapidpoint 405 Measurement Cartridge BG-CO-OX 250
10283222	06535614	10283222	Rapidpoint 405 Measurement Cartridge Full + CO-OX 250
10844811	10844811	10844811	RAPIDPoint 405 Measurement Cartridge BG + CO-OX 100
10844812	10844812	10844812	RAPIDPoint 405 Measurement Cartridge Full + CO-OX 100
10697911	10697911	10697911	RP500 S/W UPGRADE KIT V2.0
10844813	10844813	10844813	Measurement Cartridge, RAPIDPoint 500 100 (MCART LAC)
10491447	10491447	10491447	Measurement Cartridge, RAPIDPoint 500 250 (MCART LAC)
10491448	10491448	10491448	Measurement Cartridge, RAPIDPoint 500 400 (MCART LAC)
10491449	10491449	10491449	Measurement Cartridge, RAPIDPoint 500 750 (MCART LAC)
10844217	10844217	10844217	RP500 Software 2.1 Upgrade Kit
10845077	10845077	10845077	RP500 Software V2.2A Upgrade Kit
10845078	10845078	10845078	RP500 Software V2.2B (ROW) Upgrade Kit
10845079	10845079	10845079	RP500 Software V2.2B (US) Upgrade Kit
10845080	10845080	10845080	RP500 Software V2.2C (ROW) Upgrade Kit
10845284	10845284	10845284	RP500 Software V2.2C (US) Upgrade Kit
11046609	11046609	11046609	RAPIDPoint 500 Software V2.2.1A Upgrade Kit
			End of List

Siemens Healthcare Diagnostics, Inc.
Norwood, Massachusetts, USA

Susan Tibedo 26 Feb 2015

Susan Tibedo **Date**
Sr. Manager, Regulatory Affairs – POC

SIEMENS

Atitikties deklaracija

TEISĖTAS GAMINTOJAS	**Siemens Healthcare Diagnostics Inc. Tarrytown, Niujorkas 10591-5097 JAV**
GAMYBOS VIETA	**Vitrex Medical A/S Vasekaer 6-8 2730 Herlev. Danija**
GAMINYS	**Stikliniai ir plastikiniai kraujo ėmimo kapiliarai**
GAMINIO KATEGORIJA	**Žr. 1 priedą**
KLASIFIKACIJA	**Gamintojo deklaracija**
ATITIKTIES VERTINIMO PROCEDŪRA	**Taikomas III PRIEDAS**
TAIKOMI STANDARTAI	**EN ISO 14971:2001. Rizikos valdymo taikymas medicinos prietaisams. EN 375:2001. Gamintojo su reagentais, profesionalų naudojamais in vitro diagnostikai, pateikiama informacija. EN 980:2003. Grafiniai medicinos priemonių ženklinimo simboliai. EN ISO 13485:2003. Medicinos prietaisų kokybės vadybos sistema. EN 591:2001. Profesionalų naudojami in vitro diagnostikos prietaisai. Naudojimo taisyklės. EN 1658:1997. IVD instrumentų žymėjimo reikalavimai.**
DOKUMENTŲ TVARKYBOS SISTEMA Nr. LAIDA	**43-64-02 4.0**

Siemens Healthcare Diagnostics Inc.
Norwood, Massachusetts, JAV

/Parašas/
Noor Malki
Vyr. vadovas. Reguliavimo klausimai. Kontaktinis asmuo

2009 m. vasario 16 d.
Data

SIEMENS

Atitikties deklaracija

Šiuo dokumentu pareiškiame, kad pirmiau nurodytas gaminys (-iai) atitinka Tarybos direktyvos 98/79/EB dėl in vitro diagnostikos medicinos prietaisų reikalavimus. Gamintojas turi visus patvirtinamuosius dokumentus.

		1 priedas
Nuor. (BAN)	**Gaminio kodas**	**Aprašymas**
05614986	108758	Kraujo ėmimo kapiliarai, Multicap, 100 ul 500 pakuotė
08851318	471836	Kraujo ėmimo kapiliarai fiziologinėms / kraujo dujoms
01198961	473193	Kraujo ėmimo kapiliarai, Multicap, 50 x 140 ul
06493996	473646	Kraujo ėmimo kapiliarai, Multicap
07162853	473763	Kraujo ėmimo kapiliarai, Multicap, 50 x 175 ul pakuotė
01519512	473764	Kraujo ėmimo kapiliarai, Multicap
00855578	473823	Kraujo ėmimo kapiliarai, Multicap, 100 x 60 ul rinkinys
04996974	478600	Kraujo ėmimo kapiliariniai vamzdeliai, 100 ul
07938479	478604	Kraujo ėmimo kapiliariniai vamzdeliai, 140 ul
07817051	478608	Kraujo ėmimo kapiliariniai vamzdeliai, 140 ul
05974729	673394	Kraujo ėmimo kapiliarai, Multicap, 100 ul (pakuotė iš 50 vnt.)
00335434	00335434	Plastikiniai kraujo kapiliarai, Multicap, 50 x 100 ul
05656514	05656514	Plastikiniai kraujo kapiliarai, Multicap, 500 x 100 ul
04549544	04549544	Plastikiniai kraujo kapiliarai, Multicap-S
00325811	00325811	Plastikiniai kraujo kapiliarai, Multicap-S
06440221	06440221	Plastikiniai kraujo kapiliarai, Multicap, 50 x 175 ul
02043295	02043295	Plastikiniai kraujo kapiliarai, Multicap, 500 x 175 ul
08685906	478527	Dangteliai
01687040	478601	Dangteliai
01558100	478605	Dangteliai
04019456	478606	Velenėliai
09851273	478647	Adapteriai
		Sąrašo pabaiga

„Siemens Healthcare Diagnostics Inc.“ yra dabartinis teisėtas visų diagnostinių gaminių, kuriuos anksčiau gamino „Siemens Medical Solutions Diagnostics“, gamintojas. Pereinamuoju laikotarpiu, kol atnaujinamas gaminių ženklinimas etiketėmis ir klientams pateikiami dokumentai nurodant „Siemens Healthcare Diagnostics Inc.“ kaip teisėtą gamintoją, gaminiai gali būti identifikuoti ir paženklinti kaip „Siemens Healthcare Diagnostics Inc.“ arba kaip „Siemens Medical Solutions Diagnostics“ gaminiai.

Ši atitikties deklaracija taikoma ir „Siemens Healthcare Diagnostics Inc.“, ir „Siemens Medical Solutions Diagnostics“ pažymėtiems gaminiams.

Siemens Healthcare Diagnostics Inc.
Norwood, Massachusetts, JAV

/Parašas/
Noor Malki
Vyr. vadovas. Reguliavimo klausimai. Kontaktinis asmuo

2009 m. vasario 16 d.
Data

SIEMENS

Atitikties deklaracija

TEISĖTAS GAMINTOJAS	**Siemens Healthcare Diagnostics Inc. Tarrytown, Niujorkas 10591-5097 JAV**
GAMYBOS VIETA	**Smiths Medical 10 Bowman Drive Keene, NH 03431-0724 JAV**
GAMINYS	**„Rapidlyte“ švirkštas**
GAMINIO KATEGORIJA	**Žr. 1 priedą**
KLASIFIKACIJA	**Gamintojo deklaracija**
ATITIKTIES VERTINIMO PROCEDŪRA	**Taikomas III PRIEDAS**
TAIKOMI STANDARTAI	**EN ISO 13485:2003. Medicinos prietaisų kokybės vadybos sistema.**
DOKUMENTŲ TVARKYBOS SISTEMA Nr.	**43-53-02 A**
LAIDA	**5.0**

Siemens Healthcare Diagnostics Inc.
Norwood, Massachusetts, JAV

/Parašas/
Noor Malki
Vyr. vadovas. Reguliavimo klausimai. Kontaktinis asmuo

2010 m. birželio 9 d.
Data

SIEMENS

Atitikties deklaracija

Šiuo dokumentu pareiškiame, kad pirmiau nurodytas gaminys (-iai) atitinka Tarybos direktyvos 98/79/EB dėl in vitro diagnostikos medicinos prietaisų reikalavimus. Gamintojas turi visus patvirtinamuosius dokumentus.

		1 priedas
Nuor. (BAN)	**Gaminio kodas**	**Aprašymas**
08679280	08679280	„Rapidlyte“ 1 mL švirkštas
04180028	04180028	„Rapidlyte“ 3 mL švirkštas
05150149	05150149	„Rapidlyte“ 3 mL švirkštas
06194484	06194484	„Rapidlyte“ 3 mL švirkštas
08784181	08784181	„Rapidlyte“ 1 mL švirkštas
02932901	02932901	„Rapidlyte“ 1 mL švirkštas
07416421	07416421	„Rapidlyte“ 1 mL švirkštas
04909133	04909133	„Rapidlyte“ 3 mL švirkštas
00355281	00355281	„Rapidlyte“ 3 mL švirkštas
06407844	06407844	„Rapidlyte“ 3 mL švirkštas
		Sąrašo pabaiga

„Siemens Healthcare Diagnostics Inc.“ yra dabartinis teisėtas visų diagnostinių gaminių, kuriuos anksčiau gamino „Siemens Medical Solutions Diagnostics“, gamintojas. Pereinamuoju laikotarpiu, kol atnaujinamas gaminių ženklinimas etiketėmis ir klientams pateikiami dokumentai nurodant „Siemens Healthcare Diagnostics Inc.“ kaip teisėtą gamintoją, gaminiai gali būti identifikuoti ir paženklinti kaip „Siemens Healthcare Diagnostics Inc.“ arba kaip „Siemens Medical Solutions Diagnostics“ gaminiai.

Ši atitikties deklaracija taikoma ir „Siemens Healthcare Diagnostics Inc.“, ir „Siemens Medical Solutions Diagnostics“ pažymėtiems gaminiams.

Siemens Healthcare Diagnostics Inc.
Norwood, Massachusetts, JAV

/Parašas/
Noor Malki
Vyr. vadovas. Reguliavimo klausimai. Kontaktinis asmuo

2010 m. birželio 9 d.
Data