SERTİFİKA

Tam Kalite Güvence Sistemi

93/42/AT Tıbbi Cihazlar Direktifi Ek II

Firma Adı	: Genject Sağlık Ürünleri ve Kimya San. ve Tic. A.Ş
Firma Adresi	: Saray Mah. Fatih Sultan Mehmet Bulvarı No: 407/B Kazan ANKARA/ TÜRKİYE
İlgili Yönetmelikler ve Ekler	: MDD 93/42/AT Tıbbi Cihazlar Yönetmeliği - Ek II (Madde 4 Hariç)
Ürünler	: Tek Kullanımlık Sınıf IIa Steril Ürünler - Kan Gazı Şırıngası - İğneli - Hipodermik Şırınga - İğneli - Contalı / Contasız (2 ml-2,5 ml-5ml-10 ml-20 ml-50 ml) - Beslenme Enjektörü - İğnesiz (50 ml)
Sertifika Numarası	: M.2015.106.5477
Rapor Numarası	: MD.3003.IB
İlk Belgelendirme Denetimi	: 18.09.2015
Tescil Tarihi	: 26.10.2015
Yeniden Belgelendirme Tarihi/No	: -
Geçerlilik Tarihi	: 25.10.2020

APPR 2292

UDEM Uluslararası Belgelendirme
Denetim Eğitim Merkezi
San. ve Tic. Ltd. Şti.

UDEM, Listeli ürünlerin 93/42/AT direktifi Ek II, madde 4 hariç gerekliliklerinin karşıladığını beyan eder. Yukarıda adı geçen üretici Kalite Güvence Sistemi uyguladığını ve Ek II madde 5'e göre periyodik gözetim denetimleri ile sürekliliğini sağlayacağını beyan eder.Sınıf III olarak piyasaya arz edilecek ürünler için Ek II madde 4'e göre AT Tasarım İnceleme sertifikası gereklidir. Bu belgenin mülkiyet hakkı UDEM Uluslararası Belgelendirme Denetim Eğitim San. ve Tic.Ltd.Şti.'ye aittir ve istenildiğinde iade edilmelidir. Yukarıda adı geçen firma ve UDEM bu belgenin bir kopyasını Tescil tarihinden itibaren 5 yıl süre ile muhafaza etmelidir.CE Markalamanın kullanımı üretici beyanı ile firma sorumluluğundadır.Adı geçen firma onaylanmış ürün ile ilgili bütün değişiklikleri UDEM'e bildirmek zorundadır. UDEM bu belgenin geçerliliğini yenilemezse adı geçen firma söz konusu ürünün piyasaya arzını durduracaktır. Belgenin geçerliliğini www.udemltd.com.tr internet sayfasından kontrol edebilirsiniz.

CE 2292

Adres: Mutlukent Mahallesi 2070. Sokak 15/A 24 Konut No:10 Çankaya / Ankara – TÜRKİYE
Tel: +90 312 443 03 90 **Faks:** +90 312 443 03 26
E-posta: info@udemltd.com.tr www.udemltd.com.tr

Digitally signed by Pripa Natalia
Date: 2020.03.25 16:00:21 EET
Reason: MoldSign Signature
Location: Moldova

CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II

Company Name : Genject Sağlık Ürünleri ve Kimya San. ve Tic. A.Ş

Company Address : Saray Mah. Fatih Sultan Mehmet Bulvarı No: 407/B Kazan
ANKARA / TURKEY

Related Directives and Annex : MDD 93/42/EEC Medical Devices Directive - Annex II
(Excluding Section 4)

Product : Disposable Class IIa Sterile Products

- Blood Gas Syringe With Needle
- Hypodermic Syringe With Needle – Sealed /Nonsealed
  (2 ml-2,5 ml-5ml-10 ml-20 ml-50 ml)
- Nutrition Injector Without Needle (50 ml)

Certificate Number : M.2015.106.5477
Report Number : MD.3003.IB
Initial Assessment Date : 18.09.2015
Registration Date : 26.10.2015
Reissue Date/No : -
Expiry Date : 25.10.2020

UDEM International Certification
Auditing Training Centre Industry
and Trade Co. Ltd.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Co. Ltd. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned company should stop placing the product on the market. The currency of the certificate can be checked through www.udemltd.com. tr.

CE 2292

Addrres: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udemltd.com.tr

Genject
www.genject.com

CE
2292

UYGUNLUK BEYANI / DECLARATION of CONFORMITY

IMALATÇI / MANUFACTURER :

GENJECT SAĞLIK ÜRÜNLERI VE KIMYA SAN. VE TIC. A.Ş.

IMALATÇI ADRESI / MANUFACTURER ADRESS:

SARAY MAH. FATIH SULTAN MEHMET BULVARI NO: 407/B KAZAN/ANKARA – TÜRKIYE

İLETİŞİM BİLGİLERİ : TEL : +90 312 815 44 84 FAX : +90 312 815 44 94 www.genject.com

ÜRÜN ADI ve KODU / PRODUCT NAME and CODE :

KANGAZI ŞIRINGASI İĞNELİ (LİTYUM HEPARİN İÇERMEKTEDİR) /BLOOD GAS SYRİNGE WİTH NEEDLE

ÜRETIM ve SON KULLANMA TARIHI / MANUFACTURING and EXPIRY DATE

Label

PARTI NO/ LOT NUMBER :

Label

UYGULANAN STANDARTLAR / APPLIED STANDARTS

EN ISO 13485:2012, TS EN ISO 10993-1/AC:2010, TS EN 1041+A1:2014, TS EN ISO 10993-10:2011, TS EN ISO 10993-11:2010, TS EN ISO 10993-5:2010, TS EN ISO 10993-4:2010, TS EN ISO 10993-1:2010, EN ISO 14971:2012, EN 556-1:2001, TS EN ISO 7886-1:1998, TS 3521-2 EN 1707:2001, TS EN ISO 15223-1:2012, EN ISO 11137-2:2012 , EN ISO 14155:2012, TS EN ISO 11607-1:2010, TS EN ISO 11607-2:2010, EN ISO 11737-1:2006, TS EN ISO 11737-1/AC,TS EN ISO 14644-8:2013,TS EN ISO 7886-2:2006,TS EN ISO 14644-1:2001, TS EN ISO 14644-2:2006, TS EN ISO 14644-3:2006,EN ISO 62366:2008,TS 11605 EN ISO14644-1

UYGULANAN DIREKTIFLER / APPLIED DIRECTIVES

MEDICAL DEVICES DIRECTIVE 93/42/ EEC, CLASS IIA Kural 6 EK II

WE HERE WITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

FIRMA SORUMLUSU / RESPONCE OF COMPANY

BÜLENT BATTAL YER–TARIH / PLACE-DATE : ANKARA 26.10.2015

EC Certificate No/ CE Sertifika No : M.2015.106.5477

UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic.Ltd. Şti.

GMDN CODES: 58095

NOTIFIED BODY : 2292

ADRES

Mutlukent Mah. 2073 Sokak No: 10 Çankaya-ANKARA

ÇANKAYA/ ANKARA/TÜRKIYE

YETKILI IMZA / LEGALLY BINDING SIGNATURE :

BÜLENT BATTAL

Genject SAĞLIK ÜRÜN. KİMYA SAN. VE TİC. A.Ş.
Saray Mah. Fatih Sultan Mehmet Bulvarı
No: 407/B Kazan-ANKARA
Tel: 0 (312) 815 44 84 - Fax: 0 (312) 815 44 94
Kazan Mal Müdürlüğü: 394 045 4828

Yayın Tarihi: 11.11.2011

Rev. Tarihi : 26.10.2015 Rev No: 03

BUREAU VERITAS
Certification

VITREX Medical A/S

Vasekær 6-8, 2730 Herlev, Denmark

Bureau Veritas Certification Denmark A/S certifies that the Management System of the above organization has been audited and found to be in accordance with the requirements of the management system standards detailed below.

Standard

DS/EN ISO 13485:2016

Scope of certification

Development, manufacture and sales of single use glass and plastic capillary tubes and accessories for diagnostic use. Manufacture and sales of blood lancets and accessories for blood sampling and diagnostic. Marketing and sales of sutures, hypodermic syringes, Hypodermic needles, Cannulas, Needles and diabetic in-vitro medical devices.

Original cycle start date:	**14 June 2000**
Expiry date of previous cycle:	**NA**
Certification/Recertification Audit date:	**NA**
Certification/Recertification cycle start date:	**15 June 2018**

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **14 June 2021**

Certificate No.: DK009653 Version: 1 Revision date: **12 June 2018**

Certification Office: *Bureau Veritas Certification Denmark A/S*
Oldenborggade 25-31, 7000 Fredericia, Denmark

Further clarifications regarding the scope of this certificate and the applicability of the Management System requirements may be obtained by consulting the organization. To check this certificate validity, please call **(+45) 77 311 000.**

DANAK
SYSTEM Reg.nr. 5005

Declaration of Conformity

RAPIDPoint® 500 SYSTEMS

SIEMENS Healthineers

LEGAL MANUFACTURER	Siemens Healthcare Diagnostics, Inc. 511 Benedict Avenue Tarrytown, NY 10591 USA
PLACE OF MANUFACTURE	Siemens Healthcare Diagnostics, Manufacturing Ltd. Northern Road, Chilton Industrial Estate Sudbury, Suffolk CO10 2XQ, UK
EU AUTHORIZED REPRESENTATIVE	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
PRODUCT	***RAPIDPoint® 500 Systems (Instruments & Consumables)***
PRODUCT LIST	See Attachment I
CLASSIFICATION	Self-Declaration
CONFORMITY ASSESSMENT ROUTE	Annex III Applied
DOC CONTROL NO. / IDENTIFIER	63-04-02
REV	20.0

STANDARDS APPLIED

EN ISO 14971:2012	Application of Risk Management to Medical Devices
ISO 13485:2016	Medical Devices – Quality Management System Requirements - Requirements for Regulatory Purposes
EN ISO 13485:2016	Medical Device – Quality Management System Requirements – Requirement for Regulatory Purposes
EN ISO 17511:2003	In Vitro Diagonostic Medical Devcies – Measurement of Qualities of Biological samples – Metrological Traceabiliaty of Values assigned to Calibrators and Control Materials
ISO 15223 – 1: 2012	Symbols to be used with medical device labels, labeling, and information to be supplied—*PART 1: General requirements*
ISO 15223 – 2: 2012	Symbols to be used with medical device labels, labeling, and information to be supplied—Part 2: Symbol development, selection and validation
EN ISO 18113 - 1:2011	In Vitro Diagnostic Medical Devices - Information Supplied by the Manufacturer (Labeling) *PART 1: Terms, Definitions and General Requirements*

Declaration of Conformity

RAPIDPoint® 500 SYSTEMS

SIEMENS Healthineers

STANDARDS APPLIED (cont.)

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 18113 – 3:2011	In Vitro Diagnostic Medical Devices – Information Supplied by the Manufacturer (Labeling) – *PART 3: In vitro diagnostic Instruments for professional use*
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 IEC 62304:2006	Medical Device Software – Software life-cycle processes
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.
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. 61010-1:2004	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: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes*

Declaration of Conformity

RAPIDPoint® 500 SYSTEMS

SIEMENS Healthineers

STANDARDS APPLIED (cont.)

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 - *Part 1: Equipment classification and requirements*
21 CFR 1040.10	Performance Standards for Light-Emitting Products – Laser Products
21 CFR 1040.11	Performance Standards for Light-Emitting Products – Specific purpose laser products
EN 60601-1-2:2007	Medical electrical equipment - *Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests*
IEC 60601-1-2 Ed. 2.1	Medical electrical equipment - *Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests*
EN 50581:2012	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
EN 61326-1:2013 / IEC 61326-1:2012	Electrical equipment for measurement, control and laboratory use - EMC requirements - *Part 1: General requirements*
EN 61326-2-6:2013 / IEC 61326-2-6:2012	Electrical equipment for measurement, control and laboratory use - EMC requirements - *Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment*
EN 61000-3-2:2014/IEC 61000-3-2:2014	Electromagnetic compatibility (EMC) - *Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)*
EN 61000-3-3:2013 / IEC 61000-3-3:2013	Electromagnetic compatibility (EMC) - *Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection*

Declaration of Conformity

RAPIDPoint® 500 SYSTEMS

SIEMENS Healthineers

We herewith declare that the below-mention product(s) meet the provisions of the Council Directive 98/79/EC and elements specified in RoHS Directive 2011/65/EU for In Vitro Diagnostic Medical Devices, therefore, has fulfilled all requirements for applying the CE mark to the medical devices(s). The Manufacturer retains all supporting documentation.

ATTACHMENT 1

SMN	REF/BAN	PRODUCT CODE	DESCRIPTION
10283221	06535606	10283221	RAPIDPoint®405 Measurement Cartridge BG-CO-OX 250 *Note: This product is also used with RAPIDPoint 400 and 405 Systems*
10283222	06535614	10283222	RAPIDPoint®405 Measurement Cartridge Full + CO-OX 250 *Note: This product is also used with RAPIDPoint 400 and 405 Systems*
10310310	01171974	118677	RAPIDPoint® 400/405/500 Wash/Waste Cartridge *Note: This product is also used with RAPIDPoint 400 and 405 Systems*
10310323	05293926	120241	AQC Cartridge Kit *Note: This product is also used with RAPIDLab 1200 and RAPIDPoint 400 and 405 Systems*
10310469	04913211	130522	RAPIDPoint® 405 Measurement Cartridge Full + CO-OX 750 *Note: This product is also used with RAPIDPoint 400 and 405 Systems*
10313971	00724090	130523	RAPIDPoint® 405 Measurement Cartridge Full + CO-OX 400 *Note: This product is also used with RAPIDPoint 400 and 405 Systems*
10323175	05768789	130520	RAPIDPoint®405 Measurement Cartridge BG-CO-OX 750 *Note: This product is also used with RAPIDPoint 400 and 405 Systems*
10327073	07846760	130521	RAPIDPoint®405 Measurement Cartridge BG-CO-OX 400 *Note: This product is also used with RAPIDPoint 400 and 405 Systems*
10329097	8930536	129672	RAPIDPoint® 400/405/500 Wash/Waste Cartridge
10341179	09734609	118678	RAPIDPoint® 400/405/500 Wash/Waste Cartridge
10491447	10491447	10491447	RAPIDPoint® 500 Measurement Cartridge
10491448	10491448	10491448	RAPIDPoint® 500 Measurement Cartridge
10491449	10491449	10491449	RAPIDPoint® 500 Measurement Cartridge
10492730	10492730	10492730	RP500 BLOOD GAS ANALYSER
10696855	10696855	10696855	RP500 SV BLOOD GAS ANALYSER
10696857	10696857	10696857	RP500 BLOOD GAS ANALYSER
10697306	10697306	10697306	RAPIDPoint® 500 System
11416751	11416751	11416751	RAPIDPoint® 500e Blood Gas System
11416752	11416752	11416752	RAPIDPoint® 500e Blood Gas System
11416754	11416754	11416754	RAPIDPoint® 500e Blood Gas System

Declaration of Conformity

RAPIDPoint® 500 SYSTEMS

SIEMENS Healthineers

SMN	REF/BAN	PRODUCT CODE	DESCRIPTION
11416755	11416755	11416755	RAPIDPoint® 500e Blood Gas System
10697911	10697911	10697911	RP500 Software V2.0 Upgrade Kit
10844217	10844217	10844217	RP500 Software 2.1 Upgrade Kit
10844811	10844811	10844811	RAPIDPoint® 405/500 Measurement Cartridge
10844812	10844812	10844812	RAPIDPoint® 405/500 Measurement Cartridge
10844813	10844813	10844813	RAPIDPoint® 500 Measurement Cartridge
10845077	10845077	10845077	RAPIDPoint 500 Software Version 2.2A Upgrade Kit
10845078	10845078	10845078	RAPIDPoint 500 Software Version 2.2B (ROW) Upgrade Kit
10845079	10845079	10845079	RP500 Software V2.2B (US) Upgrade Kit
10845080	10845080	10845080	RAPIDPoint 500 Software Version 2.2C (ROW) Upgrade Kit
10845284	10845284	10845284	RP500 Software V2.2C (US) Upgrade Kit
11046609	11046609	11046609	RAPIDPoint 500 Software V2.2.1A Upgrade Kit
11046702	11046702	11046702	RAPIDPoint 500 Software V2.3A Upgrade Kit
11046704	11046704	11046704	RAPIDPoint 500 Software V2.3B Upgrade Kit
11046706	11046706	11046706	RAPIDPoint 500 Software V2.3C Upgrade Kit
11046708	11046708	11046708	RAPIDPoint 500 Software V2.3V Upgrade Kit
11046719	11046719	11046719	RAPIDPoint 500 Software V2.2.2A Upgrade Kit
11046720	11046720	11046720	RAPIDPoint 500 Software V2.2.2B Upgrade Kit
11046721	11046721	11046721	RAPIDPoint 500 Software V2.2.2C Upgrade Kit
11046722	11046722	11046722	RAPIDPoint 500 Software V2.2.2V Upgrade Kit
11046806	11046806	11046806	RAPIDPoint 500 Software V2.4A Upgrade Kit
11046807	11046807	11046807	RAPIDPoint 500 Software V2.4B Upgrade Kit
11046808	11046808	11046808	RAPIDPoint 500 Software V2.4V Upgrade Kit
11046813	11046813	11046813	RAPIDPoint 500 Software V2.4C Upgrade Kit
11317017	11317017	11317017	RP500 SW V. 2.3.1A Upgrade Kit
11317018	11317018	11317018	RP500 SW V. 2.3.1B Upgrade Kit
11317019	11317019	11317019	RP500 SW V. 2.3.1C Upgrade Kit
11317020	11317020	11317020	RP500 SW V. 2.3.1V Upgrade Kit
11317583	11317583	11317583	RP 500 SW V. 2.3.2A Upgrade Kit
11317584	11317584	11317584	RP 500 SW V. 2.3.2B Upgrade Kit
11317585	11317585	11317585	RP 500 SW V. 2.3.2V Upgrade Kit
11319006	11319006	11319006	RP 500 SW V. 3.0A USB Upgrade Kit
11319007	11319007	11319007	RP 500 SW V. 3.0B USB Upgrade Kit
11319038	11319038	11319038	RP500 SW V2.4.1A USB Upgrade Kit
11319039	11319039	11319039	RP500 SW V2.4.1B USB Upgrade Kit

END OF LIST

Lois Parillon

Lois Parillon
Regulatory Affairs Specialist

21-Aug-2019
DATE