SZUTEST

Digitally signed by Palii Nina
Date: 2019.02.12 12:17:35 EET
Reason: MoldSign Signature
Location: Moldova

EC CERTIFICATE

AT SERTİFİKA

According to Annex II of the Directive 93/42/EEC on Medical Devices

93/42/AT Tıbbi Cihaz, Yönetmeliği Ek II'ye göre

Full Quality Assurance System

Tam Kalite Güvencesi

Certificate Number: 2195-MED-1412002

Sertifika Numarası

Manufacturer:
Üretici

Nurteks Tekstil ve Medikal Sanayi Dış Ticaret Anonim Şirketi

Head Office /Merkez:	Köşklü Çeşme Mah. Yeni Bağdat Cad. No:124 Gebze/Kocaeli Türkiye
Branch Office /Şube:	Oruç Reis Mah. Tekstilkent Cad. Tekstilkent Sitesi B Blok No:12A/031/034 Esenler/Istanbul Türkiye

Product(s):
Ürün(ler)

Sterile Disposable Surgical Drape, Gown and Drape Sets
Steril Tek Kullanımlık Cerrahi Örtü, Önlük ve Örtü Setleri

Sterile Disposable Powder and Powder-Free Surgical Latex Gloves
Steril Tek Kullanımlık Pudralı ve Pudrasız Cerrahi Lateks Eldivenler

Reference Report No:
Referans Rapor No

2195-MED-1404008 , 2195-MED-1502010

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II(excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe and sterile conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits.
Szutest must be informed of any significant changes in the design and/or construction of the product(s).

2195 kimlik numaralı Onaylanmış Kuruluş Szutest, yukarıda belirtilen üreticinin 93/42/AT Tıbbi Cihaz Yönetmeliği EK II(madde 4 hariç) madde 3'üne göre bir kalite yönetim sistemi uyguladığını, bu yönetim sisteminin yönetmeliğin sadece bahsi geçen ürünün üretiminin güvenlik ve steril koşullarını sağlama ve devam ettirme ile ilgili gerekliliklerin karşıladığını beyan eder. Onaylanan bu kalite yönetim sistemi, 93/42/AT Tıbbi Cihaz Yönetmeliği EK II, Madde 5'e göre periyodik olarak gözetime ve habersiz saha denetimlerine tabidir.
Üretici, ürünlerinin tasarımında ve yapısında gerçekleştirdiği önemli değişiklikleri Szutest'e bildirmek zorundadır.

This EC certificate is valid till 2019-04-29.
Bu AT Sertifikası 2019-04-29 tarihine kadar geçerlidir.

Issue Date/*Yayın Tarihi:* 2014-04-30
Revision No./ *Revizyon No.:* 02
Revision Date/ *Revizyon Tarihi:* 2016-07-28

Mehmet IŞIKLAR
General Manager
Genel Müdür

This version of certificate has come into force on 2013.11.06 / *Bu sertifika versiyonu 06.11.2013 tarihinde yürürlüğe girmiştir.* 1/1 2195-MED-1412002 Rev.02

SZUTEST Teknik Kontrol ve Belgelendirme Hizmetleri Tic. Ltd. Şti.
SZUTEST Plaza, Nato Yolu Cd. Çam Sk. No:7 Ümraniye, İSTANBUL, TÜRKİYE
Tel: +90 216 - 469 46 66 Faks: +90 216 469 46 67 info@szutest.com.tr | www.szutest.com.tr

Certification of Registration

NURTEKS TEKSTİL VE MEDİKAL SAN.DIŞ TİC.A.Ş.

ADDRESS:- KÖŞKLÜ ÇEŞME MAH.YENİ BAĞDAT CAD.NO:124 GEBZE-KOCAELİ-TURKEY

QA CERTIFICATION SERVICES PVT. LTD.

Certify that the quality management system of the above organisation has been audited and found to be in accordancewith the requirements of standard detailed below.

ISO 13485:2012

PRODUCTION OF DISPOSABLE; STERILE SURGICAL GOWNS AND DRAPES, NONSTERILE GOWNS AND DRAPES, SURGICAL GLOVES
SALE OF DISPOSABLE STERILE PRODUCTS; (SURGICAL GLOVES, WOODEN TONGUE DEPRESSOR, SURGICAL BLADES, FLOWMETER, INFUSION (SERUM)SET, URINE BAG, BLOOD TRANSFUSION SET, BLOOD LANCET)
SALE OF DISPOSABLE NONSTERILE PRODUCTS; (EXAMINATION GLOVES, PE GLOVES, MASK, CAPS, SHOE COVER, WOODEN TONGUE DEPRESSOR, UNDERPADS, GOWNS AND DRAPES, NON-WOVEN PP FABRİCS)

Certificate No:- QACS-13485-TUR-NTV-0633

This certification was conducted in accordance with the QA Certification Services Pvt. Ltd. auditing and Certification procedures and it is remain valid subject to annual surveillance audits.

Certificate Issue Date : 9th January 2017 **Certificate Expiry Date : 8th January 2020**
Date of Initial Registration: 9th January 2017 **Certificate Expiry Date:- 3 Years**

Further clarification regarding the scope of this certificate of ISO 13485:2012 requirements may be obtained by consulting the organization

To Check the certificate validity please Refer Web:- (www.qacertification.asia) or call at given numbers.

Authorised Signatory

THE REPUBLIC OF TURKEY
MINISTRY OF HEALTH
(Turkish Medicines and Medical Devices Agency)

Date of issue : 22 April 2016

TO WHOM IT MAY CONCERN

HEALTH CERTIFICATE
Free Sales Certificate

Medical devices, which are in the scope of Medical Devices Directives, listed additional page(s), supplied to the market by "NURTEKS TEKSTİL VE MEDİKAL SAN. DIŞ TİC. A.Ş. (K.ÇEŞME M. YENİ BAĞDAT C. No:124 GEBZE/KOCAELİ/TÜRKİYE)" are freely sold in the Turkey and European Union and exported to other countries.

This certificate expires after 12 months from the date of issue.

Sincerely Yours

Yalçın SOYSAL, MD.
Head of Medical Device Department

Turkish Medicines and Medical Devices Agency 06520 Çankaya-Ankara-TÜRKİYE
Phone:+90 312 218 30 00 Fax: +90 312 218 30 59
Note:Please determine the section code, reference number and date in your answers http://www.titck.gov.tr

PRODUCT LIST

Barcode	Label Name	Trade Name	GMDN Code	Ref. Number
8698898290447	PATIENT GOWN SHORT SLEEVE (SIZE X-SMALL)	BROCHE	35092	
8698898290454	PATIENT GOWN LONG SLEEVE (SIZE X-SMALL)	BROCHE	35092	
8698898290836	SURGICAL UNIVERSAL SET- DISPOSABLE	BROCHE	35531	
8698898290843	SURGICAL LAPARASCOPY SET - DISPOSABLE	BROCHE	35531	
8698898290911	SURGICAL ANGIOGRAPHY SET - DISPOSABLE	BROCHE	35531	
8698898290959	SURGICAL CAESAREAN SET- DISPOSABLE	BROCHE	35531	
8698898290973	SURGICAL DELIVERY SET-DISPOSABLE	BROCHE	35531	
8698898291017	SURGICAL T.U.R. SET - DISPOSABLE	BROCHE	35531	
8698898291024	SURGICAL E.N.T. SET - DISPOSABLE	BROCHE	35531	
8698898291048	SURGICAL ARTHROSCOPY SET WITH LATEX - DISPOSABLE	BROCHE	35531	
8698898291062	SURGIAL HIP SET WITH LATEX - DISPOSABLE	BROCHE	35531	
8698898291086	STANDARD SURGICAL GOWN - DISPOSABLE	BROCHE	35778	
8698898291109	REINFORCED STERILE SURGICAL GOWN - DISPOSABLE	BROCHE	35778	
8698898291185	SURGICAL DENTAL IMPLANT SET- DISPOSABLE	BROCHE	35531	
8698898291567	SURGICAL ARTHROSCOPY SET WITH POUCHE- DISPOSABLE	BROCHE	35531	24015505100
8698898291611	SURGICAL OPHTALMIC SET - DISPOSABLE	BROCHE	35531	
8698898291659	SURGICAL GYNAECOLOGY SET - DISPOSABLE	BROCHE	35531	24015556100
8698898291697	SURGICAL ANGIOGRAPHY SET - 1 - DISPOSABLE	BROCHE	35531	
8698898292496	STERILE LATEX SURGICAL GLOVES – POWDER FREE (SIZE : 6,5)	BROCHE	40548	TGSTELPSIZ65
8698898292502	STERILE LATEX SURGICAL GLOVES – POWDER FREE (SIZE : 7)	BROCHE	40548	TGSTELPSIZ70
8698898292519	STERILE LATEX SURGICAL GLOVES – POWDER FREE (SIZE : 7,5)	BROCHE	40548	TGSTELPSIZ75
8698898292526	STERILE LATEX SURGICAL GLOVES – POWDER FREE (SIZE : 8)	BROCHE	40548	TGSTELPSIZ80
8698898292533	STERILE LATEX SURGICAL GLOVES – POWDER FREE (SIZE : 8,5)	BROCHE	40548	TGSTELPSIZ85
8698898292861	STANDARD SURGICAL GOWN – DISPOSABLE (SIZE MEDIUM)	BROCHE	35778	
8698898292878	STANDARD SURGICAL GOWN – DISPOSABLE (SIZE LARGE)	BROCHE	35778	
8698898292885	STANDARD SURGICAL GOWN – DISPOSABLE (SIZE X-LARGE)	BROCHE	35778	
8698898292892	STANDARD SURGICAL GOWN – DISPOSABLE (SIZE XX-LARGE)	BROCHE	35778	
8698898292915	REINFORCED STERILE SURGICAL GOWN – DISPOSABLE (SIZE MEDIUM)	BROCHE	35778	
8698898292922	REINFORCED STERILE SURGICAL GOWN – DISPOSABLE (SIZE LARGE)	BROCHE	35778	
8698898292939	REINFORCED STERILE SURGICAL GOWN – DISPOSABLE (SIZE X-LARGE)	BROCHE	35778	
8698898293134	NON-STERILE WELCOME SET	BROCHE	47782	

Yalçın SOYSAL, MD
Head of Medical Device Department

PRODUCT LIST

Barcode	Label Name	Trade Name	GMDN Code	Ref. Number
8698898293189	REINFORCED STERILE SURGICAL GOWN – DISPOSABLE (SIZE XX-LARGE)	BROCHE	35778	
8698898293202	PATIENT GOWN SHORT SLEEVE (SIZE SMALL)	BROCHE	35092	
8698898293219	PATIENT GOWN SHORT SLEEVE (SIZE MEDIUM)	BROCHE	35092	
8698898293226	PATIENT GOWN SHORT SLEEVE (SIZE LARGE)	BROCHE	35092	
8698898293233	PATIENT GOWN SHORT SLEEVE (SIZE X-LARGE)	BROCHE	35092	
8698898293240	PATIENT GOWN SHORT SLEEVE (SIZE XX-LARGE)	BROCHE	35092	
8698898293257	PATIENT GOWN LONG SLEEVE (SIZE SMALL)	BROCHE	35092	
8698898293264	PATIENT GOWN LONG SLEEVE (SIZE MEDIUM)	BROCHE	35092	
8698898293271	PATIENT GOWN LONG SLEEVE (SIZE LARGE)	BROCHE	35092	
8698898293288	PATIENT GOWN LONG SLEEVE (SIZE X-LARGE)	BROCHE	35092	
8698898293295	PATIENT GOWN LONG SLEEVE (SIZE XX -LARGE)	BROCHE	35092	

End Of Product List
22 April 2016

Yalçın SOYSAL, MD.
Head of Medical Device Department

PRODUCT LIST

Barcode	Label Name	Trade Name	GMDN Code	Ref. Number
8698898292229	NON-STERILE NITRILE EXAMINATION GLOVE - POWDER FREE - IVORY (SIZE LARGE)	BROCHE	40546	
8698898292267	NON-STERILE NITRILE EXAMINATION GLOVE - POWDER FREE - IVORY (SIZE X-SMALL)	BROCHE	40546	
8698898292274	NON-STERILE NITRILE EXAMINATION GLOVE - POWDER FREE - IVORY (SIZE X-LARGE)	BROCHE	40546	
8698898292311	NON-STERILE NITRILE EXAMINATION GLOVE - POWDER FREE - BLUE (SIZE X-LARGE)	BROCHE	40546	
8698898292373	(BLOOD TRANSFUSION SET)	BROCHE	38569	BSKVS105
8698898292441	STERILE LATEX SURGICAL GLOVE - POWDER (SIZE : 6,5)	BROCHE	40548	TGSTELPLI65
8698898292458	STERILE LATEX SURGICAL GLOVE - POWDER (SIZE : 7)	BROCHE	40548	TGSTELPLI70
8698898292465	STERILE LATEX SURGICAL GLOVE - POWDER (SIZE : 7,5)	BROCHE	40548	TGSTELPLI75
8698898292472	STERILE LATEX SURGICAL GLOVE - POWDER (SIZE : 8)	BROCHE	40548	TGSTELPLI80
8698898292489	STERILE LATEX SURGICAL GLOVE - POWDER (SIZE : 8,5)	BROCHE	40548	TGSTELPLI85
8698898292649	STERILE LATEX SURGICAL GLOVE - POWDER (SIZE : 6,5)	BROCHE	40548	TNSTELPLI65
8698898292656	STERILE LATEX SURGICAL GLOVE - POWDER (SIZE : 7)	BROCHE	40548	TNSTELPLI70
8698898292663	STERILE LATEX SURGICAL GLOVE - POWDER (SIZE : 7,5)	BROCHE	40548	TNSTELPLI75
8698898292670	STERILE LATEX SURGICAL GLOVE - POWDER (SIZE : 8)	BROCHE	40548	TNSTELPLI80
8698898292687	STERILE LATEX SURGICAL GLOVE - POWDER (SIZE : 8,5)	BROCHE	40548	TNSTELPLI85
8698898293110	STERILE LATEX SURGICAL GLOVE - POWDER (SIZE : 6)	BROCHE	40548	TGSTELPLI60

End Of Product List
22 April 2016

Yalçın SOYSAL, MD.
Head of Medical Device Department

CERTIFICATE

This is to certify that

Geksa-netkanie materiali, LLC

Tsentralnaya str., 3
143405 Goljovo village
Krasnogorskiy district
Moscow region
Russian Federation

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope:
Development, design and production of sterile and nonsterile disposable medical linen of various application, sterile and nonsterile disposable medical clothes of various application, sterile and nonsterile disposable medical instruments of various application, sterile and nonsterile disposable personal protective equipment of medical purpose.

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

GOST ISO 13485 - 2011 (ISO 13485 : 2003)

Certificate registration no.	31100767 MP23
Valid from	2016-12-26
Valid until	2019-12-25
Date of certification	2016-12-26

РОСС RU.31106.04ЖКП0

OOO SSU DE KU ES

Mikhail Zalunaev
Managing Director

Accredited Body: OOO SSU DEKUES, Respublikanskaya str. 3, 150003 Yaroslavl, Russian Federation

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

IQNet and
DQS GmbH Deutsche Gesellschaft zur Zertifizierung von Managementsystemen

hereby certify that the company

Geksa-netkanie materiali, LLC

Tsentralnaya str., 3
143405 Goljovo village
Krasnogorskiy district
Moscow region
Russian Federation

with the organizational units/sites as listed in the annex
has implemented and maintains a **Quality Management System**.

Scope:
Development, design and production of sterile and nonsterile disposable medical linen of various application, sterile and nonsterile disposable medical clothes of various application, sterile and nonsterile disposable medical instruments of various application, sterile and nonsterile disposable personal protective equipment of medical purpose; laminated and nonlaminated, single-layered and multi-layered, with impregnation and without impregnation, rolled polymer woven, nonwoven and geocell materials of industrial-use including for ensuring of vapor moisture proofing in construction of roofs, walls, floor structures, for soil constructions stabilization materials, for road construction and different light industry sectors as well as nonwoven materials for solving of the problems of agricultural sector, gardening, crop growing and vegetable growing.

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 9001 : 2015

Valid from	2016-12-26
Valid until	2019-12-25
Date of certification	2016-12-26

Registration number: DE-31100767 QM15

Michael Drechsel
President of IQNet

Frank Graichen
Managing Director of DQS GmbH

IQNet Partners**:
AENOR *Spain* AFNOR Certification *France* AIB-Vinçotte International *Belgium* APCER *Portugal* CCC *Cyprus*
CISQ *Italy* CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany*
FCAV *Brazil* FONDONORMA *Venezuela* ICONTEC *Colombia* IMNC *Mexico* Inspecta Certification *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland* PCBC *Poland*
Quality Austria *Austria* RR *Russia* SIGE *México* SII *Israel* SIQ *Slovenia* SIRIM QAS International *Malaysia*
SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* YUQS *Serbia*
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

* This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document
** The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

TÜV NORD

ZERTIFIKAT / *Certificate*

gem. / acc. EN ISO 13485 : 2012 + AC : 2012

Hiermit wird bescheinigt, dass die Firma / *This certifies, that the company*

Van Oostveen Medical B. V.
Herenweg 269
3648 CH Wilnis
The Netherlands

ein Qualitätsmanagementsystem nach der Norm DIN EN ISO 13485 : 2012 / EN ISO 13485 : 2012 + AC : 2012 - Medizinprodukte - Qualitätsmanagementsysteme - Anforderungen für regulatorische Zwecke - eingeführt hat und aufrechterhält. Dieses Zertifikat stellt nicht den erforderlichen Nachweis zur Anbringung der CE-Kennzeichnung dar.

has established and maintains a quality management system that meets the requirements of DIN EN ISO 13485 : 2012 / EN ISO 13485 : 2012 + AC : 2012 - Medical devices - Quality management systems - Requirements for regulatory purposes. This certificate is not an authorisation to affix the CE mark.

Geltungsbereich / *Scope*

Entwicklung, Herstellung und Vertrieb von Skalpellklingen, Skalpellen, Bluttransfusionssets, Blutlanzetten, elektronischen Blutdruckmessgeräten, Kondomen, Trachealtuben, Foley Ballons Kathetern, chirurgischen Handschuhen, Infusionssets, Intravenösen Kathetern, Nadeln, Paraffingaze, Intravenösem Infusionsbesteck Kopfhautvenen, Spritzen komplett mit Kanülen, Tuberkulinspritzen, Insulinspritzen, Digitalen Thermometern, 3-Wege-Hähnen, Aneroiden Blutdruckmessgeräten, Thermometern, Untersuchungshandschuhen, Spritzen, Urinbeuteln.
Design, Manufacturing and Distribution of Blades, Scalpels, Blood Administration Sets, Blood Lancets, Electronic Sphygmomanometers, Condoms, Tracheal Tubes, Foley Balloon Catheters, Surgical Gloves, Infusion Sets, Intravenous Catheters, Needles, Paraffin Gauze, Scalp Vein Infusion Sets, Syringes complete with Needle, Tuberculin Syringes, Insulin Syringes, Digital Thermometers, Three Way Stopcocks, Aneroid Sphygmomanometers, Thermometers, Examination Gloves, Syringes, Urine Bags.

Reg.-Nr. / *Reg.-No.* 04 221 041335
Bericht Nr. / *Report No.* 3518 0366

Gültigkeit / *Validity*
von / *from* 2016-07-30
bis / *until* 2019-03-31
(bis 2019-07-29 bei Umstellung auf EN ISO 13485:2016)
(until 2019-07-29 in case of Upgrade to EN ISO 13485:2016)
Edition 2

Essen, 2016-07-21

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

DAkkS Deutsche Akkreditierungsstelle D-ZM-12007-05-01

TÜV NORD

CERTIFICATE

Management system as per
DIN EN ISO 9001 : 2008

In accordance with TÜV NORD CERT procedures, it is hereby certified that

Van Oostveen Medical B. V.
Herenweg 269
3648 CH Wilnis
The Netherlands

applies a management system in line with the above standard for the following scope

Design, Manufacturing and Distribution of sterile and non sterile medical devices and in vitro diagnostic medical devices

Certificate Registration No. 04 100 041335
Audit Report No. 3518 0365

Valid from 2016-07-30
Valid until 2018-09-14
(until 2019-07-29 in case of Upgrade to ISO 9001:2015)
Initial certification 2004

Certification Body
at TÜV NORD CERT GmbH

Essen, 2016-07-21

This certification was conducted in accordance with the TÜV NORD CERT auditing and certification procedures and is subject to regular surveillance audits.

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.com

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

DAkkS Deutsche Akkreditierungsstelle D-ZM-12007-01-01

EG-Zertifikat / *EC-Certificate*

gem. 93/42/EWG Anhang II ohne (4) / *acc. 93/42/EEC Annex II without (4)*

Hiermit wird bescheinigt, dass die Firma / *This certifies, that the company*

Van Oostveen Medical B. V.
Herenweg 269
3648 CH Wilnis
The Netherlands

für die Produkte / die Kategorie: Liste der Produkte siehe Anlage 1
for the products / product category: List of products see annex 1

Skalpellklingen, Skalpelle, Bluttransfusionsbestecke, Blutlanzetten, elektronische Blutdruckmessgeräte, Kondome, Trachealtuben, Foley Ballon Katheter, chirurgische Handschuhe, Untersuchungshandschuhe, Urinbeutel, Infusionssets, Intravenöse Katheter, Nadeln, Paraffingaze, Intravenöses Infusionsbesteck, Kopfhautvene, Spritzen komplett mit Kanüle, Tuberkulinspritzen, Insulinspritzen, digitale Thermometer, 3-Wege-Hähne, Aneroid Blutdruckmessgeräte.

Blades, Scalpels, Blood Administration Sets, Blood Lancets, Electronic Sphygmomanometers, Condoms, Tracheal Tubes, Foley Balloon Catheters, Surgical Gloves, Examination Gloves, Urine Bags, Infusion Sets, Intravenous Catheters, Needles, Paraffin Gauze, Scalp Vein Infusion Sets, Syringes complete with Needle, Tuberculin Syringes, Insulin Syringes, Digital Thermometers, Three Way Stopcocks, Aneroid Sphygmomanometers.

ein Qualitätssicherungssystem für die Auslegung, die Fertigung und die Endkontrolle der genannten Produkte nach Maßgabe des Anhang II (ohne Abschnitt 4) der Richtlinie 93/42/EWG anwendet. Zusätzlich zur CE-Kennzeichnung muss die Kennummer der Benannten Stelle angebracht werden. Die Gültigkeit dieses Zertifikats beruht auf der Aufrechterhaltung des Qualitätssicherungssystems in Übereinstimmung mit den Anforderungen der Richtlinie und seiner Überwachung durch die Benannte Stelle gem. Anhang II Abschnitt 5. Das Zertifikat ist unter keinen Umständen übertragbar.

has established a quality system for design, production and final testing acc. to the requirements of Annex II (without section 4) of the directive 93/42/EEC. Additional to the CE-marking the notification number of the Notified Body has to be affixed. The validity of this certificate is based on the maintenance of the quality system in accordance with the requirements of the directive and its surveillance by the Notified Body according Annex II section 5. The certificate may not be transferred under any circumstances.

Reg.-Nr. / *Reg.-No.* 04 232 041335
Bericht Nr. / *Report No.* 3518 0367, 3518 0368
3518 0369

Gültigkeit / *Validity*
von / *from* 2016-07-30
bis / *until* 2019-07-29
Edition 2

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2016-07-21

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-BS-236.10.16

MOLDOVA, CHIŞINĂU, SOCIETATEA PE ACŢIUNI SA M-FARMA PENTRU FACTURI
1003600005263

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 041335

Produkte der Klasse Is *Products of class Is*	UMDNS
Spritzen 2- und 3-teilig ***Syringes 2- and 3-part***	**13-929**
Harnauffangbeutel ***Urinary Collection Bags***	**14-298**
Untersuchungshandschuhe, steril ***Examination gloves sterile***	**11-882**

Anmerkung: Für Produkte der Klasse I steril beschränkt sich das Zertifizierungsverfahren auf die Aspekte der Herstellungsschritte in Zusammenhang mit der Sterilisation und der Aufrechterhaltung der Sterilität.
Note: *For products of class I sterile the certification process is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions.*

Bericht Nr. / *Report No.* 3518 0367, 3518 0368, 3518 0369

Gültigkeit / *Validity*
von / *from* 2016-07-30
Edition 2

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2016-07-21

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

TÜV NORD

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 041335

Produkte der Klasse IIa *Products of class IIa*	UMDNS
Intravenöses Infusionsbesteck, allgemeine Verwendung ***Intravenous Administration Sets, General Purpose***	**12-157**
Katheter, intravenous, peripher ***Catheters, Intravenous, Peripheral***	**10-727**
Intravenöses Infusionsbesteck Kopfhautvene ***Intravenous Administration Sets, Scalp Vein***	**17-825**
Nadeln, hypodermisch ***Needles hypodermic***	**12-745**
Verband, nichthaftend ***Dressing, Nonadherent***	**11-325**
Spritzen 2- oder 3 teilig mit montierter oder integrierter Nadel ***Syringes 2- or 3-parts with mounted or integrated needle***	**13-922**
Spritze, Tuberkulin ***Syringes, Tuberculin***	**13-945**
Spritze, Insulin ***Syringes, Insulin***	**13-941**

Bericht Nr. / *Report No.* 3518 0367, 3518 0368, 3518 0369

Gültigkeit / *Validity*
von / *from* 2016-07-30
Edition 2

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2016-07-21

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

MOLDOVA, CHISINAU, SOCIETATEA PE ACTIUNI M-FARM 1003600005263

MINISTERUL SĂNĂTĂȚII AL REPUBLICII MOLDOVA
РЕСПУБЛИКА МОЛДОВА
МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ
SERVICIUL DE SUPRAVEGHERE DE STAT A SĂNĂTĂȚII PUBLICE
СЛУЖБА ГОСУДАРСТВЕННОГО НАДЗОРА ЗА ОБЩЕСТВЕННЫМ ЗДОРОВЬЕМ
CENTRUL NAȚIONAL DE SĂNĂTATE PUBLICĂ
НАЦИОНАЛЬНЫЙ ЦЕНТР ОБЩЕСТВЕННОГО ЗДОРОВЬЯ
2028, Кишинэу, ул. Г.Асаки 67 а
Тел. +373 22 574501, Факс +373 22 729725
IDNO 1007601001123
e-mail: cnsp@cnsp.md; anticamera@cnsp.md

DOCUMANTAȚIE MEDICALĂ / Медицинская документация
FORMULAR / *Форма* **Nr. 303-2/e**
APROBAT DE MS AL RM / *Утверждена МЗ РМ* 31.10.11 Nr. 828
Centrul de încercări de laborator acreditat în Sistemul Național de Acreditare în Domeniul Evaluării Conformității Produselor
Испытательный лабораторный центр аккредитованный Национальным Аккредитационным Центром PM MOLDAC Certificat nr. LI-044 din 02.06.2014 valabil până la 16.02.2018
Acreditat în Sistemul Ministerului Sănătății RM Аккредитованный в системе Министерства Здравоохранения PM Certificat nr. 2293 din 24.10.2014, valabil până la 24.10.2019

AVIZ SANITAR

PENTRU PRODUSELE ALIMENTARE ȘI NEALIMENTARE Nr. 2214

Санитарное заключение для пищевых и непищевых продуктов

din/*от* "20" noiembrie 2017

Prin prezentul aviz sanitar se confirmă că producerea, importul, utilizarea şi desfacerea produselor
Настоящим санитарным заключением подтверждается, что производство, ввоз, использование и реализация продукции,

Articole parafarmaceutice anexa!

sunt conforme Regulamentului (lor) sanitar (e) / соответствуют санитарному (ым) регламенту (ам) (se va indica denumirea completă a Regulamentului (lor) sanitar (e) / указать полное наименование санитарного (ых) регламента (ов)

IM nr.29 FT/1683 din 14.05.01

Organizaţia-producătoare/importatoare, ţara de origine / Организация произв./импортер, страна происхождения

Italia, DISPOTECH; Federaţia Rusă, ZAO Yaroslavli Rezinotehnica; Franţa, MAXTER; Malaysia, MAXWELL

Destinatarul avizului sanitar / Получатель санитарного заключения

„M-INTER-FARMA" SA, Moldova, Chişinău, str. Grenoble, 23

Ca temei pentru recunoaşterea conformităţii produselor Regulamentului (lor) sanitar (e) menţionat (e) au servit /
Основанием для признания продукции указанному (ым) санитарному (ым) регламентом (ам) /послужило

Demers, contract nr.50/1557 din 18.09.2015, facturi, certificate de calitate, ISO, aviz sanitar nr.2583 din 12.10.2016

(a enumera documentele de însoţire, buletinele de analiză/перечислить сопроводительные док., протоколы исслед.)

Caracteristica sanitară a produselor/*санитарная характеристика продукции:*

Parametrii (factorii) /, *показатели (факторы)*	**Normativul sanitar** / *санитарный норматив*
Articolele sunt conforme Directivei Europene 93/42/EEC	

Domeniu de utilizare / *Область применения:* scopuri medicinale, stomatologice

Condiţiile necesare de utilizare, depozitare, transportare, măsurile de securitate / *Необходимые условия использования, хранения, транспортировки, меры безопасности:*

importul, plasarea pe piaţă în condiţiile respectării legislaţiei în vigoare în Republica Moldova

AVIZUL SANITAR este valabil pînă la / *Санитарное Заключение действительно до:* 30 noiembrie 2018

ADJUNCTUL MEDICULUI ŞEF SANITAR DE STAT AL REPUBLICII MOLDOVA
Iurie PÎNZARU / *ГЛАВНОГО ГОСУДАРСТВЕННОГО САНИТАРНОГО ВРАЧА РЕСПУБЛИКИ МОЛДОВА*

(numele, prenumele / Ф.И.О.)

(semnătura / подпись)

L.Ş.

CNSP/НЦОЗ
SP 10XVI25

SSSSP/ СГНОЗ
0047192 03

Anexa la Avizul sanitar nr. 3304 **din** 30.11. **2017**

Nr.	Denumirea produselor *(наименование продукта)*	Firma producătoare, Țara
1	Aspirator de saliva 15cm N100 /DISPOTECH	Dispotech, Italia
2	Burete hemostatic steril Nr.24 10x10x10 mm	Dispotech, Italia
3	Husa p-u fotoliu stomatologic 33cm x 25cm N1	Dispotech, Italia
4	Husa pentru fotoliu stomatologic din 2 componente	Dispotech, Italia
5	Manusi din nitril / Akzenta	Dispotech, Italia
6	Manusi din latex XS, S, M, L, XL nepudrate microtexturate MEDIC-DENT	MAXTER, Malaysia
7	Manusi din nitril albastre XS, S, M, L, XL nepudrate microtexturate MEDIC-DENT	MAXWEL, Malaysia
8	Manusi din nitril verde XS, S, M, L, XL nepudrate microtexturate MEDIC-DENT	MAXWELL, Malaysia
9	MASCA in 3 straturi cu elastic DISPOTECH N50	Dispotech, Italia
10	MINI-RULOU din vata Nr.1 300 g	Dispotech, Italia
11	MINI-RULOU din vata Nr.2 300 g	Dispotech, Italia
12	MUSAMA MEDICALA	ZAO Yaroslavli-Rezinotehnica, Federația Rusă
13	Rulou de pachete p-u steriliz. instrum. 100mm X 200m.	Dispotech, Italia
14	Rulou de pachete p-u steriliz. instrum. 150mm X 200mm	Dispotech, Italia
15	Rulou de pachete p-u steriliz. instrum. 200mm X 200m	Dispotech, Italia
16	Rulou de pachete p-u steriliz. instrum. 250mm X 200m.	Dispotech, Italia
17	Rulou de pachete p-u steriliz. instrum. 50mm X 200m.	Dispotech, Italia
18	Rulou de pachete p-u steriliz. instrum. 75mm X 200m.	Dispotech, Italia
19	SERVETEL stomatologic 45cm X 33cm, 3straturi N500	Dispotech, Italia
20	SERVETEL stomatologic 50cm X 60cm rulou cu legare	Dispotech, Italia

Adjunctul medicului șef sanitar de stat al Republicii Moldova **Iurie PÎNZARU**

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

TÜVRheinland®

Registration No.: DD 60117020 0001

Report No.: 26300232 005

Manufacturer:
ZARYS International Group
Spolka z ograniczona
odpowiedzialnoscia
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

Products:
(see attachments for products and sites included)

Replaces EC Certificate, Registration No.: DD 60100191 0001

Expiry Date: 2019-06-08

The Notified Body hereby declares that the requirements of Annex V 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, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2017-03-07

Date: 2017-03-07

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Dr. K. Kluge

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

REPUBLICA MOLDOVA CHISINAU 1603600005283 S.A. PENTRU FACTURI

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60117020 0001
Report No.: 26300232 006

Manufacturer:
ZARYS International Group
Spolka z ograniczona
odpowiedzialnoscia
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

Products included:

- Sterile and non-sterile cutting gauze
- Non-sterile dressing gauze
- Sterile and non-sterile gauze swabs (with or without X-ray thread)
- Sterile and non-sterile gauze lap sponges (with X-ray thread/ with X-ray chip)
- Sterile and non-sterile gauze balls (with or without X-ray thread)
- Sterile and non-sterile gauze rolls (with or without X-ray thread)
- Sterile and non-sterile non-woven swabs (with or without X-ray thread)
- Sterile paraffin gauze dressings
- Sterile three-way stopcocks
- Sterile transfusion sets for single use
- Sterile infusion sets for single use
- Sterile extension tubes for infusion pump

Date: 2018-01-25

Notified Body

Maciej Sciera

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/6, Rev. 2

Attachment to Certificate
Registration No.: DD 60117020 0001
Report No.: 26300232 006

Manufacturer:

ZARYS International Group
Spolka z ograniczona
odpowiedzialnoscia
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

Products included:

- Sterile endotracheal tubes
- Sterile tracheostomy tubes
- Sterile breathing circuits
- Sterile catheter mounts
- Non-sterile anaesthetic masks
- Sterile laryngeal masks
- Sterile oxygen masks
- Sterile Multi-Vent masks
- Sterile non-rebreath masks
- Sterile nebulizer masks
- Sterile nasal oxygen cannulas
- Sterile nebulizer sets
- Sterile oxygen tubing
- Sterile suction catheters
- Sterile abdominal drains
- Sterile feeding tubes
- Sterile stomach and duodental tubes
- Sterile urology catheters
- Sterile surgical suction sets
- Sterile surgical suction cannulas
- Sterile syringes for single use

Date: 2018-01-25

Notified Body

Maciej Sciera

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60117020 0001
Report No.: 26300232 006

Manufacturer:
ZARYS International Group
Spolka z ograniczona
odpowiedzialnoscia
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

Products included:

- Sterile insulin syringes
- Sterile tuberculin syringes
- Sterile hypodermic needles
- Sterile insulin pen needles
- Sterile blood lancets
- Sterile IV cannulas
- Sterile needle free valves
- Sterile surgical gloves

Date: 2018-01-25

Notified Body

Maciej Sciera

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 4/6, Rev. 2

Attachment to Certificate
Registration No.: DD 60117020 0001
Report No.: 26300232 006

Manufacturer:
ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

Products included:

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Adhesive cannulla fixation dressings
- Adhesive wound dressings
- Eye pads
- Incise films
- Transparent film dressings
- Foam dressings
- Absorbent wound dressings
- Surgical gowns
- Surgical drapes
- Sets of surgical drapes
- Fluid collection pouches
- Nelaton catheters

Date: 2018-01-25

Notified Body

Maciej Sciera

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60117020 0001
Report No.: 26300232 006

Manufacturer:
ZARYS International Group
Spolka z ograniczona
odpowiedzialnoscia
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

Products included:

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Vaginal speculums
- Cervical brushes
- Urine bags
- Tongue depressors
- Guedel airways
- Intubation stylets
- Endotracheal tube holders
- Suction tubes
- Withdrawal cannulas
- Alginate dressings
- Cannula stoppers
- Umbilical cord clamps

Date: 2018-01-25

Notified Body

Maciej Sciera

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60117020 0001
Report No.: 26300232 006

Manufacturer:
ZARYS International Group
Spolka z ograniczona
odpowiedzialnoscia
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

Sites included:

ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia
spolka komandytowa
ul. Gustawa Eiffel'a 15
44-109 Gliwice
Poland

Activity: Production

Date: 2018-01-25

Notified Body

Maciej Sciera

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

TANÚSÍTVÁNY
CERTIFICATE
REND-CERT

MINŐSÉGIRÁNYÍTÁSI RENDSZER-TANÚSÍTVÁNY
QUALITY MANAGEMENT SYSTEM CERTIFICATE

Tanúsított szervezet neve / Name of certified organization:

ULTRAGEL HUNGARY 2000 KFT.

Székhely / Headquarters:

1023 Budapest, Bécsi út 4.,
Magyarország - Hungary

Telephely / Manufacturing site:

1211 Budapest, Tekercselő utca 12.,
Magyarország - Hungary

Tanúsított tevékenység:

Orvosi gélek gyártása és kereskedelme. Orvostechnikai eszközök forgalmazása.

Scope:

Production and distribution of medical gels. Distribution of medical devices.

A Rend-Cert Tanúsító és Oktató Betéti Társaság tanúsítja, hogy a fenti szervezet minőségirányítási rendszere a felsorolt tevékenységi területen megfelel a következő szabvány követelményeinek:
Rend-Cert Certification and Training Limited Partnership certifies that quality management system applied by the organization above meets the requirements of the following standard on the listed scope:

MSZ EN ISO 9001:2015
(ISO 9001:2015)

A tanúsítvány érvényes / The certificate is valid:

2018. 09. 12. – 2019. 09. 11.

A tanúsítvány száma / Reg. number:

557/2018/18_2

Kiadás / Issue: **1**
Kiadás dátuma / Issued: **2018. szeptember 12. / 12 Sept 2018**

Ügyvezető / General manager

REND-CERT Bt.
2600 Vác, Venyige u. 5.
Adószám: 21871940-2-13
Szla: 65400061-11006835

REND-CERT
MSZ EN ISO 9001:2015

REND-CERT TANÚSÍTVÁNY CERTIFICATE

MINŐSÉGIRÁNYÍTÁSI RENDSZER-TANÚSÍTVÁNY
QUALITY MANAGEMENT SYSTEM CERTIFICATE

Tanúsított szervezet neve / Name of certified organization:

ULTRAGEL HUNGARY 2000 KFT.

Székhely / Headquarters:

1023 Budapest, Bécsi út 4.,
Magyarország - Hungary

Telephely / Manufacturing site:

1211 Budapest, Tekercselő utca 12.,
Magyarország - Hungary

Tanúsított tevékenység:
Orvosi gélek gyártása és kereskedelme. Orvostechnikai eszközök forgalmazása.
Scope:
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Rend-Cert Certification and Training Limited Partnership certifies that quality management system applied by the organization above meets the requirements of the following standard on the listed scope:

MSZ EN ISO 13485:2012
(ISO 13485:2003)

Kizárások / exclusions:

7.3 – Tervezés és fejlesztés / Design and development

Nem alkalmazások / non-applicable:

7.5.3.2.2. – Aktív implantálható orvostechnikai eszközökre és implantálható orvostechnikai eszközökre vonatkozó külön követelmények/ Particular requirements for active implantable medical devices and implantable medical devices

A tanúsítvány érvényes / The certificate is valid:

2018. 05. 28. – 2019. 03. 28.

A tanúsítvány száma / Reg. number:

558/2018/18

Kiadás / Issue: **1**
Kiadás dátuma / Issued: **2018. május 28. / 28 May 2018**

Ügyvezető / General manager
REND-CERT Bt.
2600 Vác, Venyige u. 5.
Adószám: 21871940-2-13
Szla: 65400061-11006835

REND -CERT MSZ EN ISO 13485:2012

ERENLER MEDİKAL

ERENLER MEDİKAL SAN. TİC. LTD. ŞTİ.

OpStar®

OpMax®

PSET

EC Declaration of Conformity

We Erenler Medikal Co.,Ltd. herewith declares under its sole responsibility that the item of product specified below satisfies the essential requirements of the EC Medical Devices Directive 93/42/EC with amendment 2007/47/EC directive which are apply to it.

Product Name: Medical Recording/Chart Papers (ECG/CTG papers)

Type-Model: Opmask

GMDN Code: 15639

Classification: Class I, Rule I

Conformity Assesment Route: Annex VII

Applicable EU Directives: 93/43/EEC Medical Devices Devices with amendment 2007/47/EC

Applicable Standards: EN ISO 15223-1:2016, EN 1041:2009, EN ISO 14971:2012, EN ISO 13485:2012

Manufacturer: Erenler Medikal Co., Ltd

Ikitelli O.S. B. Fatih San. Sitesi 3B Blok No: 3/4 34490- Basaksehir Istanbul /Turkey

Tel : +90 212 486 00 37 (140) Fax: +90 212 486 00 38

Country of Origin: Turkey

On Behalf Of Manufacturer:

Name: Ercan Taslicukur

Position: Vise President

Date-Place: Istanbul-Turkey

Signature-Stamp:

ERENLER MEDİKAL SAN.TİC.LTD.ŞTİ. İ.O.S.B. Fatih San.Sit. 3B Blok No:3-4 Zemin Kat Başakşehir / İSTANBUL Tel 0212 486 00 37 Fax 0212 486 00 38 İkitelli V.D. 364 015 1062

CERTIFICATE

kiwa

ERENLER MEDİKAL SANAYİ TİCARET LİMİTED ŞİRKETİ

İKİTELLİ ORG. SAN. BÖL. FATİH SAN. SİT. 3B BLOK
BAŞAKŞEHİR – İSTANBUL – TURKEY

with a scope of

PRODUCTION OF MEDICAL CHART PAPERS AND VIDEO THERMAL PRINTER PAPERS, AFTER SALES SERVICES FOR INTENSIVE CARE DEVICES

Medical devices - Quality management systems - Requirements for regulatory purposes

"Following elements of the standard are excluded"
"7.3" "7.5.5" "7.5.9.2"

EN ISO 13485:2016

Certificate No	: M 10422
Initial Certification Date	: 10 June 2016
Certification Date	: 02 November 2018
Expiration Date	: 09 June 2019

General Manager

TÜRKAK
Medical Device Q.M.S.
TS EN ISO/IEC 17021-1
AB-0006-YS
TÜRKAK BDS NO
YS-524A-AF4A

Kiwa Certification Services Inc.
ITOSB 9. Cadde No. 15 Tepeören Tuzla - Istanbul - Turkey
Tel: + 90 216 593 25 75 Faks : + 90 216 593 25 74
Web: www.kiwa.com.tr E-mail: info@kiwa.com.tr

Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.
Please contact above numbers for detailed information.

Last Modified: 02 November 2018 - R 02