



EC CERTIFICATE

Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

M.2018.106.9142-1 Design Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name : Boz Tıbbi Malzeme Sanayi ve Ticaret A.Ş.
Company Address : Sağlık Mh. Sağlık 1 Sk. No:33/5 Sıhhiye Çankaya ANKARA / TURKEY
Manufacturing and Storage : Malıköy Başkent OSB Mh. 4. Cad. No:17 Sincan ANKARA / TURKEY
Storage 2 : 29 Ekim Mh. Necip Fazıl Blv. No:71 Yenikent Sincan ANKARA / TURKEY
Related Directives and Annex : 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product : Single Use, Sterile, Absorbable Haemostat Oxidized Regenerated Cellulose (ORC) - Class III
Single Use, Sterile, Absorbable Haemostat Oxidized Cellulose (OC) - Class III
GMDN : 38771

Product Types are attached.

Certificate Number : M.2018.106.9142
Report Number : MD.3532.IB
Initial Assessment Date : 07.11.2017
Registration Date : 02.01.2018
Revision Date /No : 14.01.2021/02
Expiry Date : 01.01.2023


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Auditing Training Centre Industry
and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive 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. UDEM's responsibility for class I devices covered by the EC certificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. 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



Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
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This document containing 1 (one) pages is the Annex of the Certificate with the revision number 02, with the number M.2018.106.9142 and with the registration date of 02.01.2018 and with the revision date of 14.01.2021 issued for "Boz Tibbi Malzeme Sanayi ve Ticaret A.Ş." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive.

ABSORBABLE HAEMOSTAT, OXIDIZED REGENERATED CELLULOSE (ORC) CLASS III					
PRODUCT CODE	PRODUCT CODE	PRODUCT SIZE	PRODUCT CODE	PRODUCT CODE	PRODUCT SIZE
RX0502	RX0502*	1,25cm x 5cm	BR0502	BR0502*	1,25cm x 5cm
RX0502X	RX0502X*	1,25cm x 5cm	BR0502X	BR0502X*	1,25cm x 5cm
RX1001	RX1001*	2,5cm x 2,5cm	BR1001	BR1001*	2,5cm x 2,5cm
RX1001X	RX1001X*	2,5cm x 2,5cm	BR1001X	BR1001X*	2,5cm x 2,5cm
RX1002	RX1002*	2,5cm x 5cm	BR1002	BR1002*	2,5cm x 5cm
RX1002X	RX1002X*	2,5cm x 5cm	BR1002X	BR1002X*	2,5cm x 5cm
RX1003	RX1003*	2,5cm x 7,5cm	BR2003	BR2003*	5cm x 7,5cm
RX1063	RX1063*	2,5cm x 9cm	BR2003X	BR2003X*	5cm x 7,5cm
RX2003	RX2003*	5cm x 7,5cm	BR2004	BR2004*	5cm x 10cm
RX2003X	RX2003X*	5cm x 7,5cm	BR2004X	BR2004X*	5cm x 10cm
RX2004	RX2004*	5cm x 10cm	BR2014	BR2014*	5cm x 35cm
RX2004X	RX2004X*	5cm x 10cm	BR2014X	BR2014X*	5cm x 35cm
RX2014	RX2014*	5cm x 35cm	BR3004	BR3004*	7,5cm x 10cm
RX2014X	RX2014X*	5cm x 35cm	BR3004X	BR3004X*	7,5cm x 10cm
RX3004	RX3004*	7,5cm x 10cm	BR4004	BR4004*	10cm x 10cm
RX3004X	RX3004X*	7,5cm x 10cm	BR4004X	BR4004X*	10cm x 10cm
RX4004	RX4004*	10cm x 10cm	BR4008	BR4008*	10cm x 20cm
RX4004X	RX4004X*	10cm x 10cm	BR4008X	BR4008X*	10cm x 20cm
RX4008	RX4008*	10cm x 20cm	BR6009	BR6009*	15cm x 23cm
RX4008X	RX4008X*	10cm x 20cm	BR6009X	BR6009X*	15cm x 23cm
RX6009	RX6009*	15cm x 23cm	BK1001	BK1001*	2,6cm x 2,6cm
RX6009X	RX6009X*	15cm x 23cm	BK1001X	BK1001X*	2,6cm x 2,6cm
RK1001	RK1001*	2,6cm x 2,6cm	BK1003	BK1003*	2,6cm x 10cm
RK1001X	RK1001X*	2,6cm x 2,6cm	BK1003X	BK1003X*	2,6cm x 10cm
RK1003	RK1003*	2,6cm x 10cm	BK2003	BK2003*	5cm x 7,5cm
RK1003X	RK1003X*	2,6cm x 10cm	BK2003X	BK2003X*	5cm x 7,5cm
RK2003	RK2003*	5cm x 7,5cm	BK3004	BK3004*	7,6cm x 10,2cm
RK2003X	RK2003X*	5cm x 7,5cm	BK3004X	BK3004X*	7,6cm x 10,2cm
RK3004	RK3004*	7,6cm x 10,2cm	BK6009X	BK6009X*	15,2cm x 23cm
RK3004X	RK3004X*	7,6cm x 10,2cm	BF1002X	BF1002X*	2,6cm x 5,1cm
RK6009	RK6009*	15,2cm x 23cm	BF2003X	BF2003X*	5cm x 7,5cm
RF1002	RF1002*	2,6cm x 5,1cm	BF2004X	BF2004X*	5,1cm x 10,2cm
RF2003	RF2003*	5cm x 7,5cm	BF2007X	BF2007X*	5cm x 10cm
RF2004	RF2004*	5,1cm x 10,2cm	BF3003X	BF3003X*	7,5cm x 7,5cm
RF3003	RF3003*	7,5cm x 7,5cm	BF4004X	BF4004X*	10,2cm x 10,2cm
RF4004	RF4004*	10,2cm x 10,2cm			
ABSORBABLE HAEMOSTAT, OXIDIZED CELLULOSE (OC) CLASS III					
PRODUCT CODE	PRODUCT CODE	PRODUCT SIZE	PRODUCT CODE	PRODUCT CODE	PRODUCT SIZE
ZC0502	ZC0502*	1,25cm x 5cm	ZC2014	ZC2014*	5cm x 35cm
ZC0502X	ZC0502X*	1,25cm x 5cm	ZC2014X	ZC2014X*	5cm x 35cm
ZC1001	ZC1001*	2,5cm x 2,5cm	ZC3004	ZC3004*	7,5cm x 10cm
ZC1001X	ZC1001X*	2,5cm x 2,5cm	ZC3004X	ZC3004X*	7,5cm x 10cm
ZC1002	ZC1002*	2,5cm x 5cm	ZC4004	ZC4004*	10cm x 10cm
ZC1002X	ZC1002X*	2,5cm x 5cm	ZC4004X	ZC4004X*	10cm x 10cm
ZC2003	ZC2003*	5cm x 7,5cm	ZC4008	ZC4008*	10cm x 20cm
ZC2003X	ZC2003X*	5cm x 7,5cm	ZC4008X	ZC4008X*	10cm x 20cm
ZC2004	ZC2004*	5cm x 7cm	ZC6009	ZC6009*	15cm x 23cm
ZC2004X	ZC2004X*	5cm x 7cm	ZC6009X	ZC6009X*	15cm x 23cm


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MEDICAL DEVICES CHANGE CONFIRMATION FORM

The validity of the Change Confirmation Form expires when the validity period of related EC Certificate/s expires. The Change Confirmation Form alone has no function.

Company Name : Boz Tibbi Malzeme Sanayi ve Ticaret A.Ş.

Company Address : Sağlık Sok. No:33/5 Sıhhiye Çankaya ANKARA / TURKEY

Related Directive : 93/42/EEC Medical Devices Directive

Definition of Change : The following trademarks have been added on the certificate.
REOXCEL, REOXCEL Sigma Knit, REOXCEL Fibril, BERCEL, BERCEL Dense Knit,
BERCEL Fibril, LENCEL-S, LENCEL-K, LENCEL-F, ZEOCEL, LENCEL-OC

Number of Related Certificate : M.2018.106.9142, M.2018.106.9142-1
Report Number : MD.3532
Issue Date : 14.04.2022
Revision Date : -
Revision Number : 01



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UDEM declares that the mentioned changes have been confirmed as non-significant changes according to MDR Article 120-3 and MDCG 2020-3 with this Change Confirmation Form. This form has been prepared to be shared with authorities or third parties upon request.



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Related Directive : 93/42/EEC Medical Devices Directive

Definition of Change : LENCEL trademarks have been added on the certificate.

LENCEL-S

LS-1 1,25 cm x 5 cm, LS-14 5 cm x 10 cm, LS-2 2,5 cm x 2,5 cm, LS-15 5 cm x 35 cm
LS-3 2,5 cm x 5 cm, LS-18 7,5 cm x 10 cm, LS-7 2,5 cm x 7,5 cm, LS-20 10 cm x 10 cm
LS-8 2,5 cm x 9 cm, LS-22 10 cm x 20 cm, LS-11 5 cm x 7,5 cm, LS-25 15 cm x 23 cm

LENCEL-F

LF-6 2,6 cm x 5,1 cm, LF-11 5 cm x 7,5 cm, LF-13 5,1 cm x 10,2 cm, LF-17 7,5 cm x 7,5 cm
LF-21 10,2 cm x 10,2 cm,

LENCEL-K

LK-5 2,6 cm x 2,6 cm, LK-9 2,6 cm x 10 cm, LK-11 5 cm x 7,5 cm, LK-19 7,6 cm x 10,2 cm
LK-27 15,2 cm x 23 cm

LENCEL-OC

LOC-1 1,25 cm x 5 cm, LOC-15 5 cm x 35 cm, LOC-2 2,5 cm x 2,5 cm, LOC-18 7,5 cm x 10 cm
LOC-3 2,5 cm x 5 cm, LOC-20 10 cm x 10 cm, LOC-10 5 cm x 7 cm, LOC-22 10 cm x 20 cm
LOC-11 5 cm x 7,5 cm, LOC-25 15 cm x 23 cm

Number of Related Certificate : M.2018.106.9142, M.2018.106.9142-1

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