



E C C E R T I F I C A T E

Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II

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

Manufacturing and Storage : Malıköy Başkent OSB Mah. 4. Cadde No: 17 Sincan ANKARA / TURKEY

Storage 2 : 29 Ekim Mah. Necip Fazıl Bulv. No:71 Yenikent Sincan ANKARA / TURKEY

Related Directives and Annex : MDD 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 : 05.02.2018/01

Expiry Date : 01.01.2023

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

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 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 company should stop placing the product on the market. The currency of the certificate can be checked through www.udem.com.tr.

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This document containing 1 (one) pages is the Annex of the Certificate with the revision number 01, with the number M.2018.106.9142 and with the registration date of 02.01.2018 and with the revision date of 05.02.2018 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

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