CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II

Company Name : Medbar Tıbbi Malzemeler Turizm San ve Tic. A.Ş.

Company Address : 1142 Sokak No:35 Sarnıç Gaziemir IZMIR / TURKEY

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

Product :
- Phototherapy Eye Band - Class Is
- Endoscopy Mouthpiece - Class Is
- Pouch Perforator - Class Is
- Cervix Brush - Class Is
- Cervical Brush - Class Is
- Smear Spatula - Class Is
- Limb Holder - Class Is
- Tracheostomy Fixer - Class Is
- Endotracheal Tube Fixer - Class Is
- Endometrial Suction Curette - Class Is
- Insemination Cannula - Class Is
- Surgical Drapes, Covers and Gowns - Class Is
- Cardboard Camera Cover - Class Is
- Circled Camera Cover - Class Is
- Microscope Drape - Class Is
- Video Camera Cover - Class Is
- Umbilical Cord Clamp - Class Is
- Valve Urine Bag - Class Im
- Valve Emesis Bag - Class Im
- Gastric Lavage Set - Class Im
- Karman Cannula Injector (Manuel Vacuum Aspirator)- Class IIa
- Karman Cannula - Class IIa
- Arthroscopy Set - Class IIa
- Mucous Aspirator - Class IIa
- IV Flow Controller (Controflow)- Class IIa
- Skin Marking Set - Class IIa
- Spirometer Filtered Mouthpiece - Class IIa
- Arterial Cannula - Class IIa

Digitally signed by Iarovoi Petru
Date: 2020.03.16 18:39:18 EET
Reason: MoldSign Signature
Location: Moldova

FIRMA DE PRODUCERE ŞI COMERŢ "SOGNO" S.R.L. * REPUBLICA MOLDOVA, mun. CHIŞINĂU * IDNO 1004600013854 Sogno S.R.L.

Certificate Number : M.2016.106.7000
Report Number : MD.3184.IB
Initial Assessment Date : 01.07.2016
Registration Date : 03.10.2016
Revision Date /No : -
Expiry Date : 02.10.2021

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

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CERTIFICATE

MEDBAR TIBBİ MALZEMELER TURİZM SANAYİ VE TİCARET ANONİM ŞİRKETİ

FATİH MAH. 1142 SOK. NO: 35 SARNIÇ GAZİEMİR – İZMİR – TURKEY

with a scope of

SURGICAL DRAPE PRODUCTS, IV FLOW REGULATOR PRODUCTS, KARMAN CANNULA PRODUCTS, ENDOSCOPY MOUTHPİECES, URINE COLLECTION PRODUCTS, MUCOUS ASPIRATION PRODUCTS, ARTROCOPY SETS, VOMIT/EMESIS BAG PRODUCTS, SCRUB HAND BRUSHES, FILTERED MOUTHPIECE PRODUCTS, CERVICAL BRUSH PRODUCTS, AMNIOTIC POUCH PERFORATORS, FECAL PARASITE CONCENTRATION PRODUCTS, INTENSIVE CARE PRODUCTS PROCESSES: PRODUCTION, PACKAGING, STERILIZATION, STORING DISTRIBUTION AND ETHYLENE OXIDE STERILIZATION SERVICES ARE UNDER THE SCOPE OF EN ISO 11135 STANDARD

Medical devices - Quality management systems - Requirements for regulatory purposes

"Following elements of the standard are excluded"
"7.5.3" "7.5.4" "7.5.9.2"

EN ISO 13485:2016

Certificate No	: M 10326
Initial Certification Date	: 03 October 2019
Certification Date	: 03 October 2019
Expiration Date	: 02 October 2022

General Manager

FIRMA DE PRODUCERE ŞI COMERŢ "SOGNO" S.R.L. Sogno S.R.L. IDNO 1004600013854 REPUBLICA MOLDOVA, mun. CHIŞINĂU

TÜRKAK
Medical Device Q.M.S. TS EN ISO/IEC 17021-1
AB-0006-YS

TÜRKAK BDS NO
YS-694E-E7CB

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

Last Modified: 03 October 2019 - R 00