ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV

S 3004

ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE REPUBLIK
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÈQUE
ЭЛЕКТРОТЕХНИЧЕСКИЙ ИСПЫТАТЕЛЬНЫЙ ИНСТИТУТ - ЧЕШСКАЯ РЕСПУБЛИКА

Pod Lisem 129, 171 02 Praha 8 - Troja

The Electrotechnical Testing Institute Certification Body No. 3004 for certification of management systems, accredited by the Czech Accreditation Institute, o.p.s. in accordance with ČSN EN ISO/IEC 17021, grants the

Digitally signed by Iarovoi Petru
Date: 2019.02.01 17:04:45 EET
Reason: MoldSign Signature
Location: Moldova

CERTIFICATE

No.: 8120121

for the Quality System in accordance with

EN ISO 13485:2003

to the Firm

MEDBAR TIBBİ MALZEMELER TURİZM SANAYİ VE TİCARET LTD. ŞTİ.

1142/2 Sok. No:3 Sarnıç İZMİR, Turkey

because it ascertained that the Quality System of the Firm in the field:

Manufacturing and sales of disposable non-active medical devices

in the following locations: -

complies with all requirements of the above mentioned Standard documented by the Report No.: 202152-01 of: 25.05.2012

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

The Certified Organization is subject to annual check-ups carried out by the Certification Body. Any change within the organization concerning the certification shall be followed up and approved by the Electrotechnical Testing Institute. The validity of this Certificate may be suspended or cancelled in the event of non-compliance with the Standard on the basis of which the Certificate was issued

Prague

Miroslav Sedláček
Certification and Inspection Manager

Stamp

CER/8120121

202152-01

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Pod Lisem 129, 171 02 Praha 8 - Troja

EC CERTIFICATE
PRODUCTION QUALITY ASSURANCE

issued in accordance with Annex 5 of Government Order No. 336/2004 Coll. (Annex V of Directive 93/42/EEC)

No.: MED 140058

The Electrotechnical Testing Institute, Notified Body No. 1014, on the basis of the carried audit results has decided that the quality system limited to the manufacturing aspects relevant to securing and maintaining sterile conditions established at the

manufacturer: **MEDBAR TIBBİ MALZEME TURİZM TİCARET SAN. LTD. ŞTİ.**
1142 Sok. No:35 Sarnıç Gaziemir, İzmir, Turkey

for medical device(s)

Sterile disposable non-active medical devices – class I sterile, see enclosure for products

meets the provisions of Annex 5 of Government Order No. 336/2004 Coll., which specifies technical requirements for medical devices (Annex V of Directive 93/42/EEC).

The notified body agrees with attaching its identification number 1014 to CE marking, which will be affixed to the above mentioned medical device(s) in accordance with Article 5 of Government Order No. 336/2004 Coll. (clause 17 of Directive 93/42/EEC).

The decision was based on the results presented in the audit report No. 403612-01/01 of: 19.08.2014

The approved quality system established at the manufacturer is subject to regular surveillance audits by the notified body in accordance with Annex 5 clause 4 of Government Order No. 336/2004 Coll. (Annex V clause 4 of Directive 93/42/EEC). The manufacturer must inform the notified body which approved the quality system about any intention of substantial changes to the quality system or the product range covered. In case that the conditions under which the certificate has been issued are violated, the notified body may suspend the validity of the certificate or cancel the certificate.

Edition 1

The first issue of this Certificate from with validity until
The validity of this Certificate is limited until: 23.9.2019

24.9.2014

Prague

Miroslav Sedláček
Head of Certification Body

Stamp

CERTMED140058

403612-01

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV

ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE REPUBLIK
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Pod Lisem 129, 171 02 Praha 8 - Troja

EC CERTIFICATE
PRODUCTION QUALITY ASSURANCE

issued in accordance with Annex 5 of Government Order No. 336/2004 Coll. (Annex V of Directive 93/42/EEC)

No.: MED 140061 OBL

The Electrotechnical Testing Institute, Notified Body No. 1014, on the basis of the carried out audit results has decided that the quality system established at the

manufacturer **MEDBAR TIBBİ MALZEME TURİZM TİCARET SAN. LTD. ŞTİ. 1142 Sok. No:35 Sarnıç Gaziemir, İzmir, Turkey**

for manufacturing and final inspection of medical device(s)

Arterial cannula – class IIa

meets the provisions of Annex 5 of Government Order No. 336/2004 Coll., which specifies technical requirements for medical devices (Annex V of Directive 93/42/EEC).

The notified body agrees with attaching its identification number 1014 to CE marking, which will be affixed to the above mentioned medical device(s) in accordance with Article 5 of Government Order No. 336/2004 Coll. (clause 17 of Directive 93/42/EEC).

The decision was based on the results presented in the audit report No. 403613-01/01 of: 19.08.2014.

The approved quality system established at the manufacturer is subject to regular surveillance audits by the notified body in accordance with Annex 5 clause 4 of Government Order No. 336/2004 Coll. (Annex V clause 4 of Directive 93/42/EEC). The manufacturer must inform the notified body which approved the quality system about any intention of substantial changes to the quality system or the product range covered. In case that the conditions under which the certificate was issued are violated, the notified body may suspend the validity of the certificate or cancel the certificate.

This certificate can be used for class IIb and III medical devices together with EC Type-Examination Certificate only, issued in accordance with Annex 3 of Government Order 336/2004 Coll. (Annex III of Directive 93/42/EEC).

Edition 1

The first issue of this Certificate from: with validity until
The validity of this Certificate is limited until: 16.3.2019

24.9.2014

Prague

Miroslav Sedláček
Head of Certification Body

Stamp

CER/MED140061OBL

403613-01

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV

ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE REPUBLIK
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Pod Lisem 129, 171 02 Praha 8 - Troja

EC CERTIFICATE
PRODUCTION QUALITY ASSURANCE

issued in accordance with Annex 5 of Government Order No. 336/2004 Coll.
(Annex V of Directive 93/42/EEC)

No.: MED 140060

The Electrotechnical Testing Institute, Notified Body No. 1014, on the basis of the carried out audit results has decided that the quality system established at the

manufacturer **MEDBAR TIBBİ MALZEME TURİZM TİCARET SAN. LTD. ŞTİ.**
1142 Sok. No:35 Sarnıç Gaziemir, İzmir, Turkey

for manufacturing and final inspection of medical device(s)

Sterile and non-sterile disposable non-active medical devices – class IIa, see enclosure for products

meets the provisions of Annex 5 of Government Order No. 336/2004 Coll., which specifies technical requirements for medical devices (Annex V of Directive 93/42/EEC).

The notified body agrees with attaching its identification number 1014 to CE marking, which will be affixed to the above mentioned medical device(s) in accordance with Article 5 of Government Order No. 336/2004 Coll. (clause 17 of Directive 93/42/EEC).

The decision was based on the results presented in the audit report No. 403612-03/01 of: 19.08.2014.

The approved quality system established at the manufacturer is subject to regular surveillance audits by the notified body in accordance with Annex 5 clause 4 of Government Order No. 336/2004 Coll. (Annex V clause 4 of Directive 93/42/EEC). The manufacturer must inform the notified body which approved the quality system about any intention of substantial changes to the quality system or the product range covered. In case that the conditions under which the certificate was issued are violated, the notified body may suspend the validity of the certificate or cancel the certificate.

This certificate can be used for class IIb and III medical devices together with EC Type-Examination Certificate only, issued in accordance with Annex 3 of Government Order 336/2004 Coll. (Annex III of Directive 93/42/EEC).

Edition 1

The first issue of this Certificate from with validity until
The validity of this Certificate is limited until: 23.9.2019

24.9.2014

Prague

Miroslav Sedláček
Head of Certification Body

Stamp

CER/MED140060

403612-03

List of products – class IIa

Designation	Sterile / Non-sterile
Karman cannula injector	Sterile
Karman cannula	Sterile
Arthroscopy set with pump	Sterile
Arthroscopy set without pump	Sterile
Mucus aspirator	Sterile
IV flow controller	Sterile
Skin marking set	Sterile
Medical tubes and connectors	Non-sterile
Dilator set	Sterile
T-vent	Non-sterile
Spirometer filtered mouthpiece	Non-sterile