



C E R T I F I K Á T

Zabezpečení Kvality Výroby Směrnice Rady 93/42/EHS Příloha V

Název společnosti	: Mhk Medikal Tekstil Sanayi vr Ticaret Limited Şirketi
Adresa	: Körkün Mah. Hidayet Cad. No: 23/1 Oğuzeli GAZİANTEP / TURKEY
Související normy	: Směrnice rady 93/42/EHS Příloha V
Produkt	: Sterilní jednorázové rouškování, pláště a sety - třída I
GMDN	: 35778, 47783
Číslo certifikátu	: M.2014.106.3565
Číslo zprávy	: MD.2292.YB
Datum počátečního posouzení	: 12. 3. 2014
Datum registrace	: 1. 10. 2014
Datum posouzení recertifikace:	: 26. 8. 2019
Datum reedice	: 13. 12. 2019/01
Datum revize	: -
Datum expirace	: 27. 5. 2024



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Auditing Training Centre Industry
and Trade Inc. Co.

UDEM 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 audits, defined by Annex V, section 4 of the aforementioned directive. 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 dev.ce 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 company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com.tr.



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