



EC CERTIFICATE

Production Quality Assurance Medical Devices Directive 93/42/EEC Annex V

Company Name : Tunçel Silikon San. Ve Tic. Ltd. Şti.

Company Address : İvedik O.S.B. Mahallesi 1537. Sok. No:33 Yenimahalle ANKARA / TURKEY

Related Directives and Annex : 93/42/EEC Medical Devices Directive - Annex V

Product : Sterile Chest Drainage Set - Class Is

Trademarks : TUNÇEL® , EDDA®

GMDN : 10817

Product Types are attached.

Certificate Number : M.2020.106.13894
Report Number : MD.3340.IB
Initial Assessment Date : 19.08.2020
Registration Date : 17.09.2020
Revision Date /No : -
Expiry Date : 27.05.2024



UDEM International Certification
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 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 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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This document containing 1 (one) pages is the Annex of the Certificate with the number M.2020.106. 13894 and with the registration date of 17.09.2020 issued for "Tunçel Silikon San. Ve Tic. Ltd. Şti." 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

EDDA® Products List

No	Product Reference Number	Product Name	Measure	GMDN Code
1	TS20GDS-2000	EDDA Single Use Sterile Chest Drainage Set	2000 cc	10817
2	TS20GDS-700	EDDA Single Use Sterile Chest Drainage Set	700 cc	10817

TUNÇEL® Products List

No	Product Reference Number	Product Name	Measure	GMDN Code
1	TS20TGDS-2000	TUNCEL Single Use Sterile Chest Drainage Set	2000 cc	10817
2	TS20TGDS-700	TUNCEL Single Use Sterile Chest Drainage Set	700 cc	10817