



EC CERTIFICATE

Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

Company Name : Permed Sağlık Ürünleri Gıda Tekstil Hayvancılık San ve Tic. Ltd. Şti.

Company Address : Işıklar Köyü Tesdicikırı Mevkii Çan Yolu Caddesi No:25/1A,
ÇANAKKALE / TURKEY

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

Product : Versafix Meniscal Repair System - Class IIb

Brand Name : GRANDUS

GMDN : 45061

Product Types are attached.

Certificate Number : M.2021.106.14653

Report Number : MD.4100.IB

Initial Assessment Date : 11.12.2020

Registration Date : 25.05.2021

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 II, excluding section 4 of the 93/42/EEC Directive 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. 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



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This document containing 1 (one) pages is the Annex of the Certificate with the number M.2021.106.14653 and with the registration date of 25.05.2021 issued for "Permed Sağlık Ürünleri Gıda Tekstil Hayvancılık 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

1 pirkimo dalis

REF NO	PRODUCT NAME	GMDN CODE
✓ 122-305	VersaFix Meniscal Repair System Standard	45061
✓ 122-306	VersaFix Meniscal Repair System Right Curved	
✓ 122-307	VersaFix Meniscal Repair System Left Curved	
122-308	VersaFix Suture Passer and Cutter	