



# C E R T I F I C A T E

## EC Design-Examination Certificate

### 93/42/EEC Directive of Medical Devices Annex II, Section 4

With the expire of the certificate M.2016.106.7035 the validity of the certificate M.2016.106.7035-1 will also end.

Company Name : Gmd Group Medikal Sanayi ve Ticaret Anonim Şirketi  
Company Address : İkitelli Osb Mah. İsdök Sosyal Tesis 2 Sk. B Blok 1 B 7 Başakşehir  
İSTANBUL / TURKEY  
Related Directives and Annex : 93/42/EEC Medical Devices Directive - Annex II (Section 4)  
Product :- Polyglycolic Acid(PGA) (DAMACRYL®) Synthetic, Coated, Braided, Absorbable, With or Without Needle Sterile Surgical Suture, Violet or Undyed - Class III  
- Poly (Glycolide-Co-Lactide) / Polyglactin - 910(PGLA), (DAMACRYL 910®) Synthetic, Coated, Braided, Absorbable, With or Without Needle Sterile Surgical Suture, Violet or Undyed - Class III  
- Poly(P-Dioxanone)(PDO) (DAMADIOXANONE®) Synthetic, Monofilament, Absorbable, With or Without Needle Sterile Surgical Suture, Violet or Undyed - Class III  
- Poly (Glycolide-Co-Lactide) / Polyglactin - 910(PGLA RAPID) (DAMACRYL RAPID®) Synthetic, Coated, Braided, Absorbable, With or Without Needle Sterile Surgical Suture, Undyed Fast Absorbable - Class III  
- Poly (Glycolide-Co-Caprolactone) [Poliglecaprone 25](PGCL), (DAMACAPRONE®) Synthetic, Monofilament, Absorbable, With or Without Needle Sterile Surgical Suture, Violet or Undyed - Class III  
- Polypropylene (PP), (DAMALENE®) Synthetic, Monofilament, Non-Absorbable, With or Without Needle Sterile Surgical Suture, Blue Dyed- Class III  
- Polyester(PE), (DAMAESTER®) Braided, Coated, Non-Absorbable, With or Without Needle Sterile Surgical Suture, Green or Undyed - Class III

GMDN : 13908, 17471, 16584, 45814, 13909, 13906

Certificate Number : M.2016.106.7035-1

Report Number : MD.3148.YB

Initial Assessment Date : 27.09.2016

Registration Date : 25.10.2016

Recertification Assessment Date : 13.12.2019

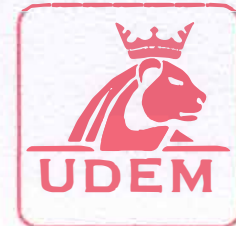
Reissue Date / No : 25.03.2020/01

Revision Date /No : -

Expiry Date : 27.05.2024



UDEM International Certification  
Auditing Training Centre Industry  
and Trade Inc. Co.



The EC design examination certificate refers to the above mentioned product. UDEM hereby declares that the requirements of Annex II, section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applied a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the aforementioned directive. 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 validity 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](http://www.udem.com.tr).

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