CERTIFICATE

EC Design-Examination Certificate

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

With the expire of the certificate M.2019.106.11775 the validity of the certificate M.2019.106.11775-1 will also end.

Company Name	: Dispofarma İlaç Sanayi ve Ticaret Ltd. Şti.
Company Address	: İvedik Organize Sanayi Bölgesi Ağaç İşleri Sitesi 1333. Cadde No:51 Yenimahalle ANKARA / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Section 4)
Product	: Urethral Lubricant Gel with 2 % Lidocaine HCL, Sterile - Class III
Trademark	: Dispogel, Urojell, PD Gel
GMDN	: 37717

This certificate is issued due to the scientific opinion of Ministry of Health (Number: 68869993-511.14-E.59941, Date: 10.04.2019) according to 93/42/EEC Annex I 7.4.

Digitally signed by Ionascu Andrei
Date: 2022.12.09 12:14:51 EET
Reason: MoldSign Signature
Location: Moldova

Product Types are attached.

Certificate Number	: M.2019.106.11775-1
Report Number	: MD.3684.IB-1
Initial Assessment Date	: 27.12.2018
Registration Date	: 11.04.2019
Revision Date /No	: 27.05.2020/01
Expiry Date	: 10.04.2024

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.

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This document containing 1 (one) pages is the Annex of the Certificate with the revision number 01, with the number M.2019.106.11775-1 and with the registration date of 11.04.2019 and with the revision date of 27.05.2020 issued for "Dispofarma İlaç Sanayi ve Ticaret 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

Ref No	Product
DSP-2	Dispogel ® 6ml Urethral Lubricant Gel with 2% Lidocaine HCl (within Syringe)
URJ-2	Urojell® 6ml Urethral Lubricant Gel with 2% Lidocaine HCl (within Syringe)
PDG-2	PD Gel® 6ml Urethral Lubricant Gel with 2% Lidocaine HCl (within Syringe)
DSP-3	Dispogel ® 11 ml Urethral Lubricant Gel with 2% Lidocaine HCl (within Syringe)
URJ-3	Urojell® 11 ml Urethral Lubricant Gel with 2% Lidocaine HCl (within Syringe)
PDG-3	PD Gel® 11 ml Urethral Lubricant Gel with 2% Lidocaine HCl (within Syringe)
DSP-4	Dispogel ® 8.5 g Urethral Lubricant Gel with 2% Lidocaine HCl (within Accordion Bottle)
URJ-4	Urojell® 8.5 g Urethral Lubricant Gel with 2% Lidocaine HCl (within Accordion Bottle)
PDG-4	PD Gel® 8.5 g Urethral Lubricant Gel with 2% Lidocaine HCl (within Accordion Bottle)
DSP-1	Dispogel ® 12.5 g Urethral Lubricant Gel with 2% Lidocaine HCl(within Accordion Bottle)
URJ-1	Urojell® 12.5 g Urethral Lubricant Gel with 2% Lidocaine HCl (within Accordion Bottle)
PDG-1	PD Gel® 12.5 g Urethral Lubricant Gel with 2% Lidocaine HCl (within Accordion Bottle)

UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş
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