



# EC CERTIFICATE

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

Company Name : Jendental-Ukraine LLC

Company Address :  
Production Site : Boryspilka Street, 9, Build 61, Kyiv 02099, Ukraine  
Head Office, R&D Department : Sadova 191 Str., Building 2, Kyiv 02132, Ukraine

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

Product : Non-Sterile Dental Materials For Restorative and Prosthetic Dentistry,  
"Ultropaline" Universal Dental Ceramics - Class IIa

GMDN : 38764, 42483, 16187

Product Types are attached.

Certificate Number : M.2021.106.14406  
Report Number : MD.3216.IB  
Initial Assessment Date : 03.03.2020  
Registration Date : 01.04.2021  
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 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](http://www.udem.com.tr).



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This document containing 1 (one) pages is the Annex of the Certificate with the number M.2021.106.14406 and with the registration date of 01.04.2021 issued for “Jendental-Ukraine LLC” 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

BRAND	CATALOG NUMBER	PRODUCT NAME	GMDN
<b>Dental materials for restorative and prosthetic dentistry</b>			
JenD	2571	Jen-Radiance	38764
JenD	2572	Jen-Radiance Molar	38764
JenD	2573	Jen-LC Flow	38764
JenD	2574	Jen-Radiance FCP	38764
JenD	2575	Jen-Radiance WA	38764
JenD	2576	Jen-Favorite LC	38764
JenD	2577	Jen-Rainbow	38764
JenD	2641	Jen-Unibond	42483
JenD	2642	Jen-Unibond SE	42483
<b>“Ultropaline” Universal dental ceramics</b>			
JenD	2711	Ultropaline	16187
JenD	2712	ZR Ultropaline	16187

