



EC CERTIFICATE

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

Company Name : İnci Dental Tıbbi Malzeme San. ve Tic. Ltd. Şti.

Company Address : Defterdar Mah. Otakçılar Cad. E Blok Sit. No:74/4 Eyüpsultan
İSTANBUL / TURKEY

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

Product : Non-Sterile Capsule Amalgam - Class IIa
Non-Sterile Powder Amalgam - Class IIa

GMDN : 34836

Product Types are attached.

Certificate Number : M.2016.106.6845
Report Number : MD.3141.YB
Initial Assessment Date : 15.04.2016
Registration Date : 22.06.2016
Recertification Assessment Date : 02.10.2019
Reissue Date / No : 03.02.2020/01
Revision Date /No : 25.03.2021/01
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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REVISION REVIEW APPROVAL FORM

When the validity period of the EC/ Design (if exists) Certificate to which it is attached expires, the validity period of the Revision Review Approval Form will also expire. Revision Review Approval Form has no function if used alone.

Company Name : İnci Dental Tıbbi Malz. San. ve Tic. Ltd. Şti.
Company Address : Deftardar Mah. Otakçılar Cad. E Blok Sit. No:74/4 Eyüpsultan
İSTANBUL / TURKEY
Related Directive : 93/42/EEC Medical Devices Directive

Definition of Change : The annex of english certificate has been corrected.

CAPSULE AMALGAMS

%45 Silver Capsule Amalgam Filling Material Spill 1	34836
%45 Silver Capsule Amalgam Filling Material Spill 2	34836
%45 Silver Capsule Amalgam Filling Material Spill 3	34836
%45 Silver Capsule Amalgam Filling Material Spill 5	34836
%45 Silver Zinc Free Capsule Amalgam Filling Material Spill 1	34836
%45 Silver Zinc Free Capsule Amalgam Filling Material Spill 2	34836
%45 Silver Zinc Free Capsule Amalgam Filling Material Spill 3	34836
%45 Silver Zinc Free Capsule Amalgam Filling Material Spill 5	34836
%55 Silver Capsule Amalgam Filling Material Spill 1	34836
%55 Silver Capsule Amalgam Filling Material Spill 2	34836
%55 Silver Capsule Amalgam Filling Material Spill 3	34836
%55 Silver Capsule Amalgam Filling Material Spill 5	34836
%69,2 Silver Capsule Amalgam Filling Material Spill 1	34836
%69,2 Silver Capsule Amalgam Filling Material Spill 2	34836
%69,2 Silver Capsule Amalgam Filling Material Spill 3	34836
%69,2 Silver Capsule Amalgam Filling Material Spill 5	34836
%69,2 Silver Zinc Free Capsule Amalgam Filling Material Spill 1	34836
%69,2 Silver Zinc Free Capsule Amalgam Filling Material Spill 2	34836
%69,2 Silver Zinc Free Capsule Amalgam Filling Material Spill 3	34836
%69,2 Silver Zinc Free Capsule Amalgam Filling Material Spill 5	34836

POWDER AMALGAM

%45 Silver Powder Amalgam Filling Material	34836
%69,2 Silver Powder Amalgam Filling Material	34836

Certificate Number Which It is Attached : M.2016.106.6845

Report Number : MD.3141

Issue Date : 07.10.2021

Revision Date : -

Revision Number : 00

Revision Review Approval Form has been prepared for the products mentioned above. UDEM declares that the listed products are non-significant changes according to MDR Article 120-3 and MDCG 2020-3. This form has been prepared to be shared with authorized authorities and 3rd parties upon request.


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