



SANİTER®

GIDA - ÇEVRE BİLİMİ GÖZETİM VE MÜHENDİSLİK
HİZMETLERİ TURİZM TİCARET LİMİTED ŞİRKETİ



Test
TS EN ISO/IEC 17025
AB-0009-T

accredited by.
TÜRKAK
TURKISH ACCREDITATION AGENCY

AB-0009-T

1678-15

06-15

Report No
Sample Code/Item No
The Purpose of the Analysis
Customer Name
Address
Project Name
Sample's ;
Type
Serial-Batch/ Number
Purchase Order
Packing Shape/Type
Quantity
Date of Manufacture
Expiration Date
Producing Company/Brand
The location of sampling
Temperature of sample
Ambient/delivery temperature
Date Received /Arrived
Date of analysis
Date of report

ANALYSIS REPORT
:1678-15
:556
:SPECIAL REQUESTS
:MODE MEDİKAL SAN. VE TİC. LTD. ŞTİ.
:ABDİ İPEKÇİ CAD. NO:58 BAYRAMPAŞA-İSTANBUL
:-
: DENTAL İMPLANT 4,7X13 DS İMPLANT
: 0215-010
:-
:ORIGINAL
:2 pcs.
:02/2015
:-
:Mode Medikal San ve Tic Ltd Şti
:-
:-
:21°C
:26.02.2015
:26.02.2015
:26.06.2015

The results of the accelerated aging test of "DENTAL İMPLANT 4,7X13 DS İMPLANT" samples that you have sent on, February 26, 2015 are given below. The test objective is determination of shelf life by using accelerated aging method ASTM F 1980. First, samples of "DENTAL İMPLANT 4,7X13 DS İMPLANT" are placed in a calibrated oven preheated to the required temperature. Samples that are aged according to the required accelerated aging time are then taken out of the oven. These samples are then evaluated by visual examination.

RESULT: Not detected physical deformation at the samples. Sterility test result is appropriate.
REAL TIME AGING (RT) : 5 YEARS (1825 DAYS)
% RELATIVE HUMIDITY : 45
AMBIENT TEMPERATURE (T_{RT}) : 22 °C
ACCELERATED AGING TEMP. (T_{AA}) : 65 °C
ARRHENIUS EQUATION Q₁₀ : 2
ACCELERATED AGING TIME (AAT) : 93 days
OVEN TYPE : NUVE FN 120 INCUBATOR

ANALYSIS	RESULTS	LIMITS	**COMPLIANCE STATUS	MEASUREMENT LIMITS	RECOVERY	UNCERTAINTY OF MEASUREMENT	ANALYSIS METHOD
Aerobic mesophilic bacteria* (30 ± 2 °C 14 d Tryptone soy broth)	No Growth	No Growth	C	-	-	-	ISO 11737-2
Anaerobic mesophilic bacteria* (30 ± 2 °C 14 d Fluid thioglycollate medium)	No Growth	No Growth	C	-	-	-	ISO 11737-2
Negative control (30 ± 2 °C 14 d TSB ve FTM)	No Growth	No Growth	C	-	-	-	ISO 11737-2
Positive control: Bacillus atropheus (30 ± 2 °C 14 d TSB ve FTM)	Growth	Growth	C	-	-	-	ISO 11737-1

*:Accredited analysis by TÜRKAK.

**::Compliance Status:C:Conformed NC:Non Conformed NE:No Evaluation

Çağlayan Çatal
Department Chief

Confirmable
Sonay Çantürk
Lab.Tech. Manager

Ebru Şişman
Sample Acceptance and Reporting
Department Chief

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F.02.34/Rev.5/03.12.14/24.08.10

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