

TRUSTED QUALITY MARK 2017-2018 REPORT OF ANALYSIS

Name of Manufacturer: NucleOSS - Şanlılar Tıbbi Cihazlar Medikal Kimya San. Tic. Ltd. Şti.

Analyzed Product(s): T6 D3.5 L12.0 LOT 1703794 (ex factory)
T6 D3.5 L12.0 LOT 1704199 (ex factory)
T6 D3.5 L12.0 LOT 1704198 (ex factory)
T6 D4.1 L8.0 LOT 1601466
T6 D3.5 L14.0 LOT 1700755

Analysis Period: August - September 2017

Type of Analysis: Full-Size High-Resolution SEM Imaging (FSHR)
Area + Spot-Imaging by Backscattered Electrons (BSE)
Quantitative and Qualitative Elemental-Analysis (EDS)

Project manager:

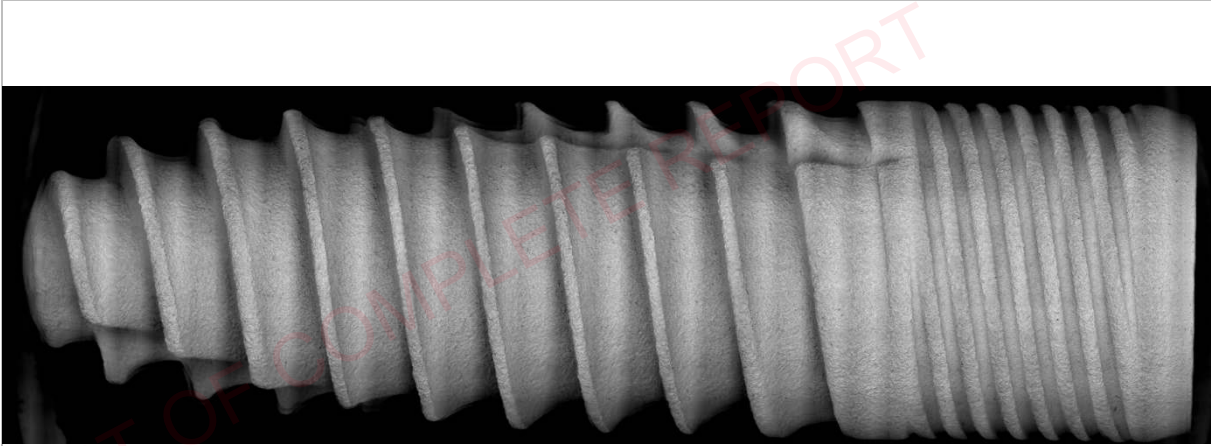
Dr. med. dent. Dirk U. Duddeck Managing Director CleanImplant Foundation
Phone: +49 171 54 77 99 1 Mail: duddeck@cleanimplant.com

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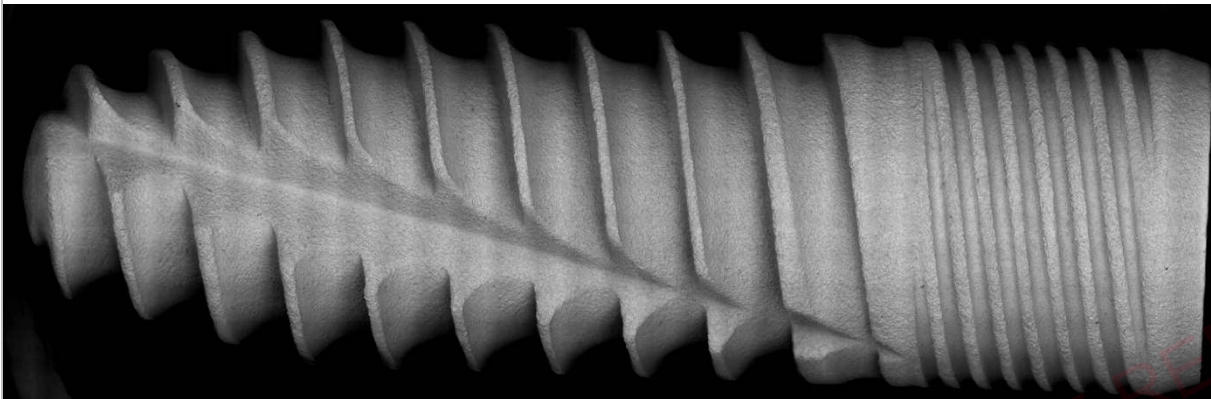
1 ABSTRACT / SUMMARY

1.1 FSHR SEM Images of Samples ex factory

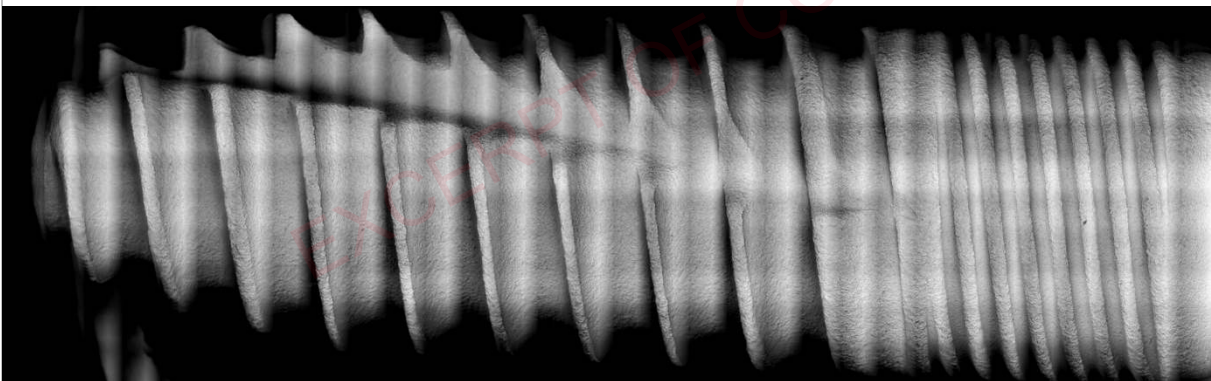
Images are not to scale



Sample #1: T6 D3.5 L12.0 LOT 1703794; valid 2022.05



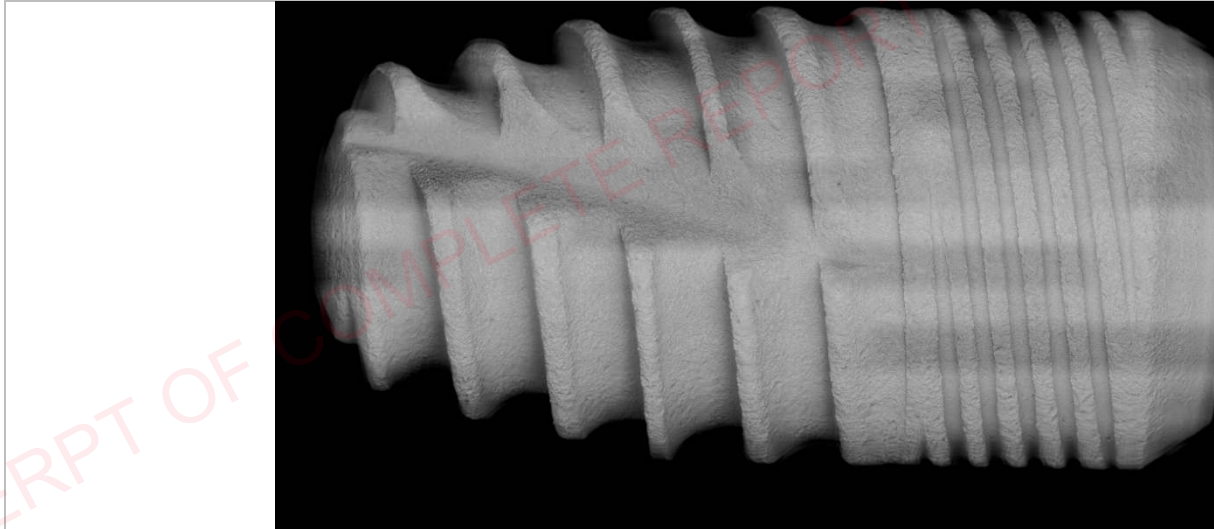
Sample #2: T6 D3.5 L12.0 LOT 1704199; valid 2022-06



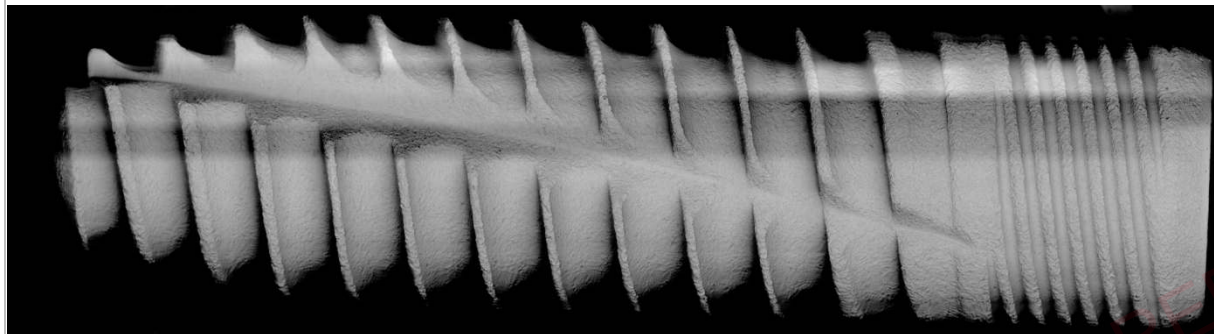
Sample #3: T6 D3.5 L12.0 LOT 1704198; 2022-06

1.2 FSHR SEM Images of Samples Provided from Practices

Images are not to scale



Sample #4: T6 D4.1 L8.0 LOT 1601466; valid 2021-03



Sample #5: T6 D3.5 L14.0 LOT 1700755; valid 2022-01

1.3 Summary

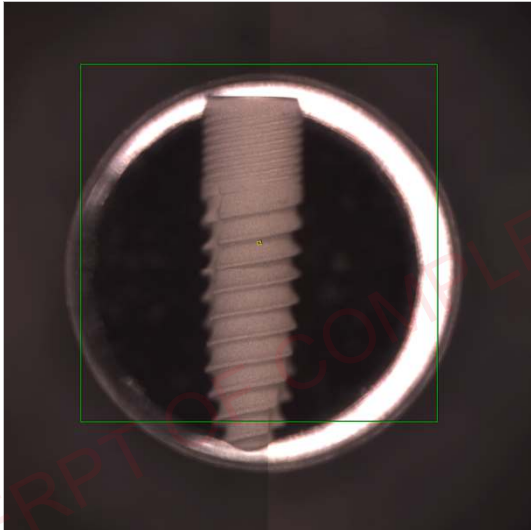
The implant samples showed only 2-7 minor organic particles on each implant, with a size of less 5- 30 μm in an angle of view of 120° . Some of these particles showed embedded titanium filings and/or aluminum oxide particles (e.g. p.78). Single Al_2O_3 particle on one implant that also revealed traces of silicon (p. 22+23). Many grooves appear in the BSE imaging like foreign body material, however, showed in higher magnification only the core material titanium

Requested sufficient clinical documentation was provided.

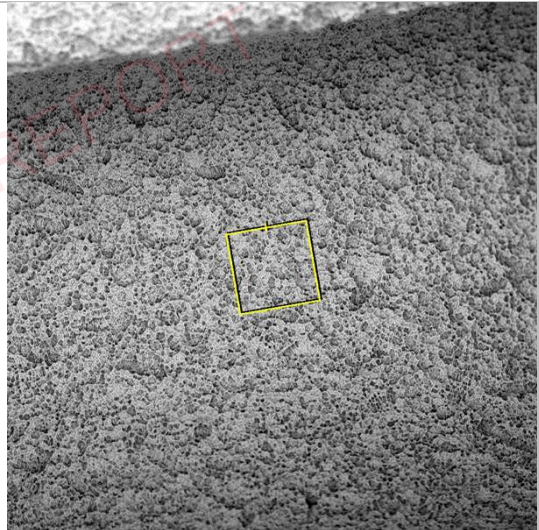
Conclusion: The implant "T6" from NucleOSS meets the criteria for the CleanImplant Trusted Quality Mark 2017-2018

3.2 SEM Imaging Sample #1

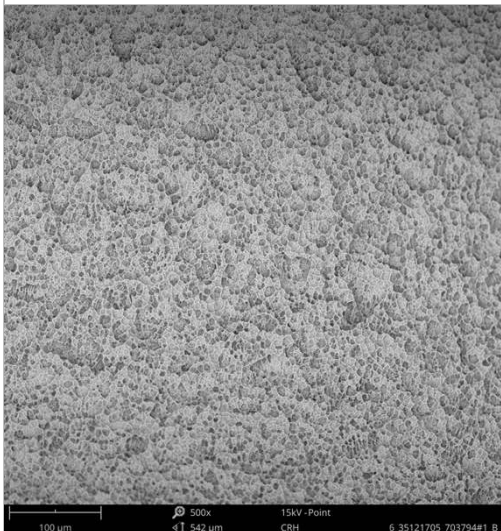
3.2.1 SEM Images Implant Body



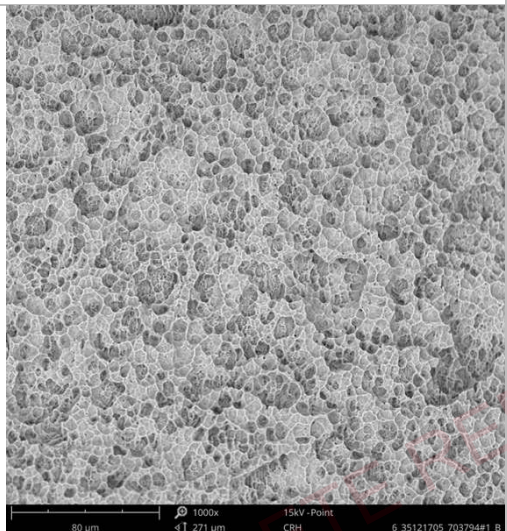
Phenom camera



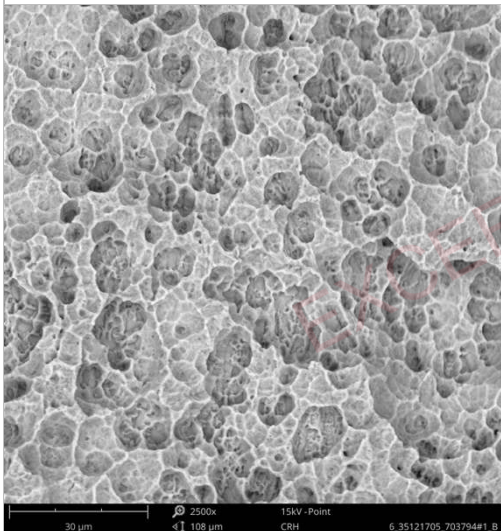
Field of view



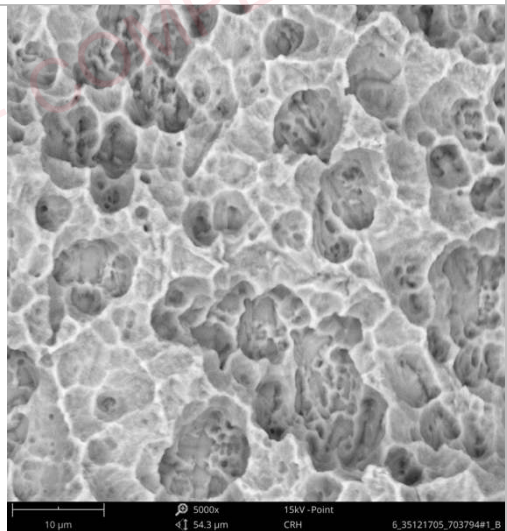
500x



1.000x



2.500x



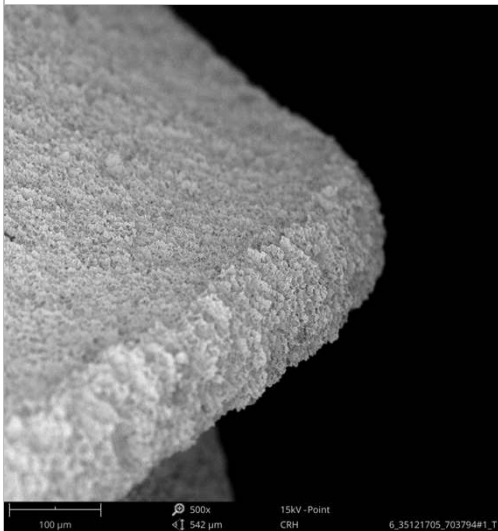
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3.2.2 SEM Images Implant Thread

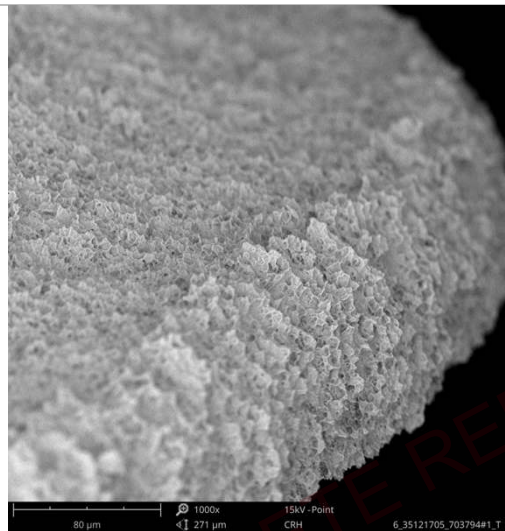


Phenom camera

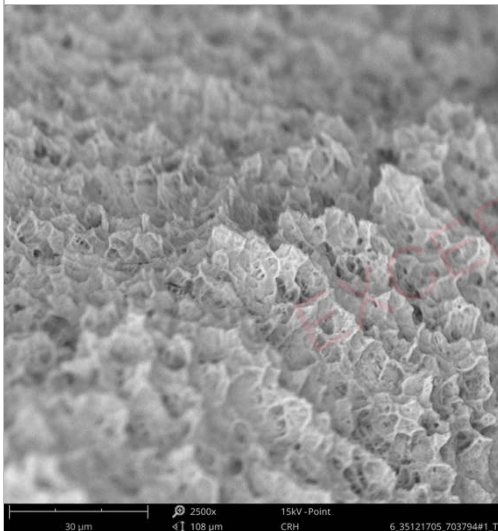
Field of view



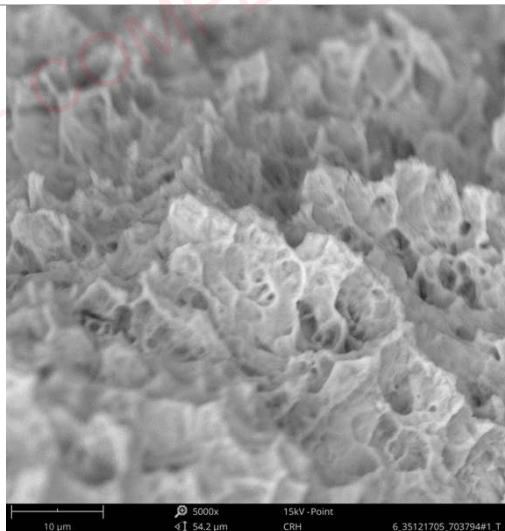
500x



1.000x



2.500x



5.000x

8 Synopsis

Name of Manufacturer:	NucleOSS - Şanlılar Tıbbi Cihazlar Medikal Kimya San. Tic. Ltd. Şti.
Analyzed Product(s):	T6 D3.5 L12.0 LOT 1703794 (ex factory) T6 D3.5 L12.0 LOT 1704199 (ex factory) T6 D3.5 L12.0 LOT 1704198 (ex factory) T6 D4.1 L8.0 LOT 1601466 T6 D3.5 L14.0 LOT 1700755
Investigator/s:	Dr. Dirk U. Duddeck
Analyses carried out by:	mmri.berlin - medical materials research institute berlin
Analysis period:	August - September 2017
Methodology:	Phenom proX Scanning Electron Microscope, equipped with high-sensitivity backscattered electron detector; EDS Analysis detector type: Silicon Drift Detector (SDD) Thermoelectrically cooled (LN ₂ free), Detector active area: 25 mm ² , Ultra-thin Silicon Nitride (Si ₃ N ₄) X-ray window allowing detection of elements C to Am, Energy resolution Mn Kα ≤ 140 eV, Max. Input count rate: 300,000 cps
Summary/Conclusions:	<p>The implant samples showed only 2-7 minor organic particles on each implant, with a size of less 5- 30 µm in an angle of view of 120°. Some of these particles showed embedded titanium filings and/or aluminum oxide particles (e.g. p.78). Single Al₂O₃ particle on one implant that also revealed traces of silicon (p. 22+23). Many grooves appear in the BSE imaging like foreign body material, however, showed in higher magnification only the core material titanium</p> <p>Requested sufficient clinical documentation was provided.</p> <p>Conclusion: The implant "T6" from NucleOSS meets the criteria for the CleanImplant Trusted Quality Mark 2017-2018.</p>

9 COORDINATING INVESTIGATOR(S) SIGNATURE(S)

TITLE: Report of Analysis for the CleanImplant
"Trusted Quality Mark 2017-2018"

AUTHOR OF REPORT: Dr. Dirk U. Duddeck

Principal Investigator and Managing Director CleanImplant Foundation
Guest researcher at the Charité University Medicine Berlin - Campus Benjamin Franklin
Department of Prosthodontics, Head: Prof. Dr. Florian Beuer

eMail: duddeck@cleanimplant.com

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the analyses.

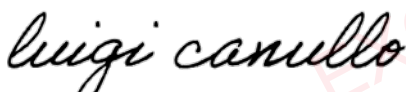
PRINCIPAL INVESTIGATOR: Dr. Dirk U. Duddeck

DATE: October 02, 2017



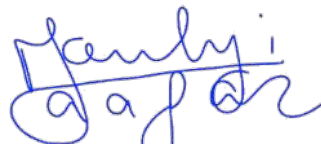
10 PEER REVIEW SIGNATURES

We confirm that the information provided in this report meets the Criteria for the CleanImplant Trusted Quality Mark 2017-2018.



October, 4, 2017

Dr. Luigi Canullo PhD



October 4, 2017

Prof. Jaafar Mouhyi

Date / Peer Reviewer

Date / Peer Reviewer