

To: all whom may concern

Subject: Declaration on chemical composition of medical devices

Dental Implant System ROOTT:

- ROOTT R
- ROOTT C
- ROOTT CS
- ROOTT B
- ROOTT BS
- ROOTT M
- ROOTT P
- ROOTT S

Mentioned above dental implant types of ROOTT System are made from Titanium Alloy (Ti 6-Al 4-V ELI) which corresponds to the Grade 23. The chemical composition list below:

Titanium Alloy according to ASTM F136 and ISO 5832-3:	
Chemical components	Composition % (mass/mass)
Iron, max	0.25
Oxygen, max	0.13
Aluminium	5.5–6.50
Vanadium	3.5–4.50
Titanium	balance

This Titanium Alloy considered to be used in any biomedical application, particularly for implantable components, because of its biocompatibility and good fatigue strength.

This Titanium Alloy regulated by the International Standards:

- EN ISO 5832-3 "Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminum 4-vanadium alloy".
- ASTM F136 "Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)".

No other materials are incorporated into Dental Implant System ROOTT.

Authorized Signatory:

On behalf of TRATE AG

Director of Quality,
Ms. Vladlena Shulezhko
30.05.2023

