



ISLAMIC REPUBLIC OF IRAN
MINISTRY OF HEALTH AND MEDICAL EDUCATION

IRAN FOOD AND DRUG ADMINISTRATION



<<CERTIFICATE FOR EXPORT OF MEDICAL DEVICE>>

Certificate No:88.00203050

Issue Date: 2017.12.11

Product(s): Bionic Dental Implant System

Manufacturer: Nic Kasht Asia Co.

Address of Manufacturer: No 110, Bidestan Sepidar Blvd, Golestan Blvd, Kharazmi Industrial Park, Tehran Iran

This certificate is hereby issued pursuant to the article 81 of the Medical Device Regulation Booklet of I.R.IRAN, and the above-mentioned manufacturer complies with the medical device Good Manufacturing Practice (GMP) requirements (based on ISO 13485) which are currently in force in the Islamic Republic of Iran. This product has been registered and allowed to be sold in I.R.IRAN. The manufacturer is committed to carryout export legally.

(This certificate is valid for one year from the date of issuance)

Reza Masaeli
Director General of
Medical Equipment Dep.

000203050

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Management System Certification Body No. MSCB-105

CERTIFICATE

No. 17-A-0541 IGC

This is to certify that the Quality Management System of

Nik Kasht Asia

of

NO 110, sepidar st, bidestan blv, golestan blv, phase 2, kharazmi industrial complex, 35th km semnan road, IRAN

Company Reg. No.: 431989

has implemented and documented a quality management system in compliance with the requirements of the standard

ISO 9001:2015

for

Manufacture of Dental Implants to the Bone

The certificate is issued on the basis of the results mentioned in the pertinent audit report. Validity of the certificate is conditionally limited by positive results of surveillance audits, which the certified company committed to undergo.

This certificate can be invalid if the certificate holder does not fulfill the conditions set out in the certification agreement.

Initial issue date: Oct. 10, 2017
Expire date: Oct. 09, 2020



Betty Kim

Betty, Kim
Head of Certification Body



Management System Certification Body No. MSCB-105

CERTIFICATE

No. 17-B-0235 IGC

This is to certify that the Quality Management System of

Nik Kasht Asia

of

NO 110, sepidar st, bidestan blv, golestan blv, phase 2, kharazmi industrial complex, 35th km semnan road, IRAN

Company Reg. No.: 431989

has implemented and documented a quality management system in compliance with the requirements of the standard

ISO 13485:2016

for

Manufacture of Dental Implants to the Bone

The certificate is issued on the basis of the results mentioned in the pertinent audit report. Validity of the certificate is conditionally limited by positive results of surveillance audits, which the certified company committed to undergo.

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Initial issue date: Oct. 10. 2017

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Betty Kim

Betty, Kim
Head of Certification Body