TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60099567 0001

Report No.: 12022681 002

Manufacturer:
Nakanishi Inc.
700 Shimohinata, Kanuma,
TOCHIGI, 322-8666
JAPAN

Products: Instruments and Equipment in Dental and Surgical Fields

(see attachments for products included)

Replaces Approval, Registration No.: HD 60093350 0001

Expiry Date: 2019-05-06

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2015-11-24

Date: 2015-11-24

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Dipl.-Ing. O. Masur

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197

REPUBLICA MOLDOVA mun. CHIȘINĂU «VISIOSYSTEMS» IDNO 1006600037327 RĂSPUNDERE LIMITATĂ