

DECLARATION OF CONFORMITY

No. DC-1-07J-GR-1

MANUFACTURER

NAKANISHI INC.

700 Shimohinata, Kanuma-shi, Tochigi-ken 322-8666, Japan

AUTHORIZED EU REPRESENTATIVE

NSK EUROPE GmbH Elly-Beinhorn-Strasse 8 65760 Eschborn Germany

MEDICAL DEVICE

Surgical Rotary Cutting Instruments

Product Name: Surgic Pro

Model No.: Surgic Pro, Surgic Pro +

Classification: Class II a (Rule 9)

NAKANISHI INC. is exclusively responsible for the declaration of conformity.

The serial number applied to this product is managed by the "Shipping history data".

The undersigned hereby declares that the medical device as specified above conforms with the essential requirements listed in Annex I of EC Directive 93/42/EEC.

The declaration of conformity is based in the EC Directive 93/42/EEC Annex II and Supported by the TÜV Rheinland LGA Products GmbH, Tillystrasse 2, 90431 Nürnberg (0197) Annex II certificate, with reference to articles 1 and 3 of directive 93/42/EEC.

Certificate Registration No: HD 60022568 0001

And, this declaration of conformity includes the EC Directive 2006/42/EC.

Tochigi, Japan: Jul 5, 2011

Yoshihiro Kanno, Quality Assurance Dept. Manager



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