

EC DECLARATION OF CONFORMITY

Manufacturer: NORITAKE DENTAL SUPPLY CO., LIMITED
300 Higashiyama, Miyoshi-cho, Miyoshi, Aichi 470-0293,
Japan

European Representative: EMERGO EUROPE
Molenstraat 15, 2513 BH, The Hague,
The Netherlands

Product: **Trade Name:** Noritake Super Porcelain EX-3
Noritake Super Porcelain Ti-22
SCREENING PORCELAIN
CERABIEN
CERABIEN ZR
CZR PRESS
EX-3 PRESS
CZR PRESS LF
EX-3 PRESS LF

Description: Dental Porcelain

Classification: Class IIa
Rule 8 according to Annex IX of the MDD

Conformity Assessment Route: Annex II applied (excluding section 4)

We herewith declare that the above-mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer and the notified body.

General applicable directives: Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

Standards: Harmonized Standards (published in the Official Journal of the European Communities) applicable to this product are:

BSEN1641:2004	Dentistry - Medical devices for dentistry - Materials
ISO7405:1997	Dentistry – Preclinical evaluation of biocompatibility of medical devices used in dentistry – Test methods for dental materials
ISO10993-1:2003	Biological evaluation of medical devices - Part 1: Evaluation and testing

Notified Body: SGS UK
ID #: 0120

EC Certificate: Standard: EN ISO13485:2003
EC Certificate
Issued by: SGS UK

Signature: 
Name Kiyoshi Yoshida
Position Executive officer NORITAKE DENTAL SUPPLY CO., LIMITED
Date: May 28th 2010