



TERCÜME

T.C.  
İZMİR 25. NOTERLÜĞÜ  
1456 Sokak No: 18/B Alsancak - İZMİR  
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SGS

EC Sertifikası Üretim Kalite Güvenlik Sistemi: Sertifika

JP06/40024

Üretim tesisi 300 Higashiyama, Miyoshi-cho, Miyoshi  
Aichi 470-0293, Japonya

№28457

Adresinde yerleşik

Kuraray Noritake Dental Inc.'nin

Aşağıdaki cihazlar için:  
Dental Porselen  
Dental Seramik Blok

**93/42/EEC Yönetmeliği**  
Medikal cihazlar, Ek II (Bölüm 4 hariç) hakkında

Yönetim Sistemi

Şartlarına göre değerlendirilmiş ve onaylanmıştır.

Bu sertifika kapsamı Sınıf III cihazlarının piyasaya sürülmesi için Ek II (Bölüm 4)'e göre bir EC Tasarım İnceleme Sertifikası gereklidir.

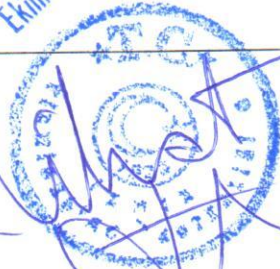
Bu sertifika 1 Nisan 2012'den başlayarak 7 Kasım 2015 tarihine kadar geçerlidir ve tatmin edici gözetim kontrollerine tabi olarak geçerli sayılacaktır.  
14 Eylül 2013 tarihinden önce yeniden onaylama kontrolü.  
Sayı 6, 19 Ekim 2006'dan beri onaylı.

Onaylama, JP/YOK/4321 sayılı raporlara dayanır.

SGS United Kingdom Ltd., Tanınmış Kuruluş No. 0120  
( imza )

202B Worle Parkway, Weston-super-Mare, BS22 6WA UK  
SGS CE 13 0311

22 Ekim 2013



Mihet TÜRKÜĞLU  
Müv. Yeminli Başkatipliği

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EC Certificate Full Quality Assurance System: Certificate  
Certificate JP06/40024

The management system of

## Kuraray Noritake Dental Inc.

Manufacturing Site 300 Higashiyama, Miyoshi-cho, Miyoshi,  
Aichi 470-0293 Japan

has been assessed and certified as meeting the requirements of

### Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

For the following products

**Dental Porcelain  
Dental Ceramic Block**

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.

This certificate is valid from 1 April 2012 until 7 November 2015 and  
remains valid subject to satisfactory surveillance audits.  
Re certification audit due before 14 September 2013  
Issue 6. Certified since 19 October 2006

Certification is based on reports numbered JP/YOK/4321

Authorised by

**SGS United Kingdom Ltd, Notified Body 0120**

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Nihat TÜRKÖĞLU  
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