

100 LAT – DOŻYWOTNIA GWARANCJA

KEROX DENTAL UDZIELA DOŻYWOTNIEJ GWARANCJI NA WADY FABRYCZNE MATERIAŁU

Elementy wyprodukowane z dwutlenku cyrkonu Kerox Dental nie mają prawa ulec uszkodzeniu, jeśli są wytworzone zgodnie z instrukcją producenta, oraz zasadami profesjonalnego postępowania. Gwarancja na materiał może jedynie być egzekwowana, jeśli zostanie stwierdzona zgodność postępowania według instrukcji zawartej na opakowaniu produktu, dostępnej także na stronie www.kerxdental.net

AUTORYZACJE DLA DYSTRYBUCJI

CE CERTYFIKAT
TÜV Rheinland

FDA CERTYFIKAT
Food and Drug Administration – Department of Health & Human Services

CERTYFIKATY FIRMY

ISO 9001:2008 CERTYFIKAT
TÜV Rheinland

EN ISO 13485:2003 + AC:2009 CERTYFIKAT
TÜV Rheinland

100 LAT
DOŻYWOTNIEJ GWARANCJI

Certificate

Standard: **ISO 9001:2008**

Certificate Register No.: **75 100 10651**

TÜV Rheinland InterCert Kft. certifies:

Certificate Holder: **Kerox Kft.**
Homokbányás út 77,
H-2049 Diósd
Hungary
Site: H-1117 Budapest, Budaörsi út 111.

Scope: design, development, production and distribution of Single Lever Ceramic Mixing-Cleaning Cartridges for Faucets, Wax Mixers for thermoclastic applications, and manufacturing and sale of Zirconia Blanks for dental applications.

An audit was performed. Proof has been furnished that the requirements according to ISO 9001:2008 are fulfilled.

Validity: The certificate is valid from **2012.02.03** until **2015.02.02**.

Budapest, 2012.02.03

[Signature]
TÜV Rheinland InterCert
H-1132 Budapest, Váci út 48/A-B
www.tuv.com

 

Exhibit

Indications for Use

510(k) Number (if known): K120852

Device Name: Zirconia Blanks (Zirconar)

Indications for Use:
Zirconia Blanks are indicated for crowns, multi-unit bridges and inlay bridges.
Applications include both anterior and posterior bridges.

Prescription Use AND/OR Over-The-Counter Use
(Per 21CFR 901 Subpart D) (21CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-CR)
Division of Biotechnology, General Hospital
Infection Control, Dental Division

510(k) Number: K120852



APPROVAL
EC Directive 93/42/EEC, Annex V, Article 3
Quality Assurance System Production

Registration No.: **OD 69241702 0001**

Report No.: **28212232 001**

Manufacturer: **Kerox Kft.**
Homokbányás út 77,
H-2049 Diósd
Hungary

Scope: Manufacturing of Sincostar® Zirconia blanks for dental applications

Date of expiry: 2017-02-07

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex V, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex V, Article 4 of the aforementioned EC Directive, and can be used by the company with the manufacturer's Declaration of Conformity.

Budapest, 2012-02-08

[Signature]
Zoltán Ábrányos M.D.
Certifier

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Notified under No. 1008 to the EC Commission.
The CE marking may be used if all relevant and effective EC Directives are complied with.