

Full Quality Assurance System
Directive 93/42/EEC on Medical devices, Annex II excluding (4)

CE Certiso Ltd. (NB 2409) certifies that the following manufacturer's quality management system concerning to the listed devices and device categories meets the requirements of the related requirements of the directive.

Name of the manufacturer:

KEROX Ipari és Kereskedelmi Kft.

Headquarters: **2038 Sóskút, Kerox u. 1., Hungary**

Scope:

PMMA discs for temporary dentures
KEROX PREMIA PMMA CAD/CAM DISC

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
PMMA disc	KEROX PREMIA PMMA CAD/CAM DISC	construction of temporary crowns and bridges; modeling and control of final bridges; construction of removable denture base plate, teeth whitening splint, braces, inlay / onlay	Monocolor Multilayer 2-layer	Ila

This certificate is valid only in case of successfully conducted annual surveillance audits.

ID number of the related audit report: 180-CE-180912

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Expires:
29 March 2024

CE Certiso

Orvos- és Kórháztechnikai
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