

Production Quality Assurance
Directive 93/42/EEC on Medical devices, Annex V

CE Certiso Ltd., Organisation for Certification and Testing on the Field of Medical and Hospital Engineering (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 with the aspects of securing sterile conditions.

Name of the manufacturer:

Goldent Hungary Kft.

Headquarters: **H-2120 Dunakeszi, Alagi majori út 3. HUNGARY**

Scope:

Cross-linked acrylic denture teeth

The certificate covers the following devices:

Name of the device	Model	Intended use	Risk class	GMDN category
Denture teeth	Classic	denture	II.a	38643
Denture teeth	Premium	denture	II.a	38643
Denture teeth	Exclusive	denture	II.a	38643

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

ID number of the related audit report: 50-CE-130228

Issue: 1

Issued: 20 June 2013

First issued: 20 June 2013


Start date of certified status: 20 June 2013

Expires:

19 June 2018

CE Certiso

Orvos- és Kórháztechnikai
Ellenőrző és Tanúsító Kft.
H-2040 Budaörs, Gyár u. 2.
Adószám: 23147049-2-13


Valter PAPP, Dr.
General Manager



QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate number: 144621-16-06-20

Name of certified organisation:

Goldent Hungary Kft.

Headquarters:

H-2120 Dunakeszi, Alagi majori út 3. HUNGARY

Scope:

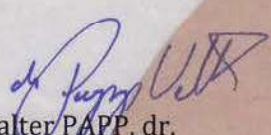
Manufacture and distribution of cross-linked acrylic denture teeth

CE Certiso Ltd. certifies that the quality management system applied by the organisation above meets the requirements of the following standard on the listed scope:

**ISO 13485:2003
(EN ISO 13485:2012)
excluding Design and development (7.3)**

Issue: 1
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Expires:
19 June 2019



Valter PAPP, dr.
General Manager



QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate number: 144620-16-06-20

Name of certified organisation:

Goldent Hungary Kft.

Headquarters:

H-2120 Dunakeszi, Alagi majori út 3. HUNGARY

Scope:


Manufacture and distribution of cross-linked acrylic denture teeth

CE Certiso Ltd. certifies that the quality management system applied by the organisation above meets the requirements of the following standard on the listed scope:

ISO 9001:2008
(EN ISO 9001:2008)
excluding Design and development (7.3)

Issue: 1
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15 September 2018



Valter PAPP, dr.
General Manager

