

EC CERTIFICATE
Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V

No. 5-765-500-1406

**National Institute for Quality- and Organizational Development
in Healthcare and Medicines**

Directorate of Device Testing and Clinical Engineering (EMKI)

certifies that the manufacturer:

CHEMIDENTAL Piotr Piechucki
ul. Orla 10-12/3
95-200 Pabianice
Poland

for the products / product category:

Dental materials

applies a quality system which meets the requirements of Directive 93/42/EEC concerning medical devices, Annex V.

Registry number of the related audit report: **42-37172-2013**

This certificate is valid until **2019-06-24** supposed that the results of the regular yearly surveillance audits are satisfactory.

Issued by EMKI as a Notified Body with identification number **1011**.

This certificate is valid only with the attachment.

Budapest, 2014-06-25




General Director


Certification Office



EMKI 1146

The authenticity and validity of the certificate are verifiable at EMKI.

Gyógyszerészeti és Egészségügyi Minőség- és Szervezetfejlesztési Intézet
National Institute for Quality- and Organizational Development in Healthcare and Medicines
Eszközminősítő és Kórháztechnikai Igazgatóság
Directorate of Device Testing and Clinical Engineering



H-1125 Budapest, Diós árok 3.
Tel.: +36 1 356 1522 Fax: +36 1 375 7253

Internet: www.gyemszi.hu

ATTACHMENT TO EC CERTIFICATE

Page 1 of 1

Additional information for Certificate No. 5-765-500-1406

The certificate is valid for the following products:

<i>Dental materials</i>	<i>Class</i>
EUGENOL	Ila
ZINC OXIDE	Ila
CITRIC ACID 40 %	Ila
HEMOALUSTAT SOLUTION / GEL 25%	Ila
DENTAL ETCHING GEL 37% PHOSPHORIC ACID	Ila
SODIUM HYPOCHLORITE 2% and 5%	Ila
EDTA 17% SOLUTION / CREAM	Ila
CHLORHEXIDINE DIGLUCONATE 2%	Ila

The detailed description of the product is kept by EMKI under No. 42-37172-2013.

Issue: 1

Date: 2014-06-25

First issued: 2014-06-25

General Director



Certification Office



EMKI

Gyógyszerészeti és Egészségügyi Minőség- és Szervezetfejlesztési Intézet
National Institute for Quality- and Organizational Development in Healthcare and Medicines
Eszközminősítő és Kórháztechnikai Igazgatóság
Directorate of Device Testing and Clinical Engineering



H-1125 Budapest, Diós árok 3.
Tel.: +36 1 356 1522 Fax: +36 1 375 7253

Internet: www.gyemszi.hu