



## CE CERTIFICATE

### EC DECLARATION OF CONFORMITY

We, GAP Research Co Ltd of: Unit 2, Ebbsfleet Industrial Estate, Stonebridge Road, Gravesend, Kent. DA11 9DZ, England., hereby declare that the medical device specified below conform with the Essential Requirements of Annex I of the Medical Devices Directive 93/42/EEC incorporated as a statutory instrument into English law (SI 618). The medical device are specifically manufactured under a quality system complying with the requirements of Annex V and VII of that Directive, but annex VI in the case of MGS Prophy Brushes and MGS Prophy Rubber Cups.

**A) List of devices and classification according to Annex IX class I**

INVASIVE DEVICES - Rule 5, Second Indent, Short term

Refit  
Sof-Grip

INVASIVE DEVICES - Rule 5, First Indent, Transient use

MGS Mouthwash Tablets  
MGS Prophy Paste  
MGS Fun Mouthwash  
Smile  
Clove-Gel

**B) List of class IIa devices in accordance with MDD 93/43/EEC Annexe IX, Rule 8**

Tooth-fil  
First Aid Dental Kit

**list of class IIa devices in accordance with MDD 93/43/EEC Annexe IX, Rule 5**

MGS Prophy Brushes  
MGS Prophy Cups

The products are manufactured by GAP Research Co Ltd., in England.  
It is hereby declared that the devices concerned meet the provisions of the Medical devices Directive 93/42/EEC which apply to them.

Name of Accreditation body: BSI Quality Assurance.

Mr A S Photay  
Technical Director

Date: 28<sup>th</sup> April 2009



Unit 2, Ebbsfleet Estate, Stonebridge Road, Gravesend, Kent, DA11 9DZ.

Tel: 01474 560618

Fax: 01474 564418

E-mail: [gapdental@btconnect.com](mailto:gapdental@btconnect.com)



# Certificate

## Production Quality Assurance

No. CE 51688



Issued to:

**Gap Research Co. Ltd  
Unit 2 Ebbsfleet Estate  
Stonebridge Road  
Northfleet  
Kent  
DA11 9DZ  
United Kingdom**

In respect of:

**The manufacture of temporary tooth filling material and prophy cups and brushes for dental professional use.**

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex V, Section 3.2.

For and on behalf of the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):

A handwritten signature in black ink, appearing to read 'D. Ford', with a horizontal line underneath.

David Ford, Director, Healthcare and Testing Services

First Issued: **22 Sep 1999**

Date: **23 Oct 2009**

Expiration Date: **21 Sep 2014**

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### Conditions of Approval

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate unless specifically agreed with BSI.

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