**EC DECLARATION OF CONFORMITY**
**According to Annex V and Annex VII of MDD 93/42/EEC**

TF15 08 May 2006
GMDN 46939

**GC EUROPE N.V.**
**Research Park**
**Interleuvenlaan 33**
**B-3001 Leuven**
**Belgium**

We ensure and declare under our sole responsibility that the product :

**FREEGENOL TEMPORARY PACK**

to which this declaration relates, is in conformity with the following standards or other normative documents :

**ISO 3107:2011** **Dentistry - Zinc oxide/eugenol cements and zinc oxide/non-eugenol cements**

**EN ISO 13485:2016 Medical Devices -Quality Management Systems- Requirements for Regulatory Purposes**

and meets the provisions of Council Directive 93/42/EEC concerning Medical Devices which apply to it, and is manufactured in accordance with the technical documentation.

This product is Class IIa according to rule 8 of annex IX of the Council Directive.

Notified Body: British Standards Institution (n°2797).

Leuven, .....09/03/2021.....
Date

.....

Mario Minale
Head of Regulatory Affairs
On behalf of GC EUROPE N.V.

## LIST OF PRODUCTS

| Article Code | New Article code | Description |
|---|---|---|
| 000178 | 10004993 | Freegenol Temporary Pack for GCA CE |
| 009561 | 10005567 | FREEGENOL TEMPORARY PACK 1-1PKG AU |
| 000087 | 10000009 | Freegenol Temporary Pack |
| 003440 | 10000675 | Freegenol Temporary Pack EEP |
| 901519 | 10003751 | PROMO Fuji Plus Caps A3 + Freegenol WEP |
| 901520 | 10003752 | PROMO Fuji Plus Caps A3 + Freegenol EEP |
| 136501 | 10003920 | FREEGENOL TEMPORARY PACK |