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

TF125 19 February 2016

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

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

G-CEM LinkForce

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

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.

G-CEM LinkForce 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
009540	10001338	G-CEM LinkForce System Kit 1x G-CEM LinkForce A2 8.7g (5ml), 1x G-CEM LinkForce Translucent 8.7g (5ml), 30x GC Automix Tip Regular, 5x GC Automix Tip for endo, 1x G-Multi PRIMER (5ml), 1x G-Premio BOND (5ml), 1x G-Premio BOND DCA (3ml), 1x GC ETCHANT 4.8g (3.6ml), 1x G-CEM LinkForce Try-In Paste A2 1.5g (1.2m), 1x G-CEM LinkForce Try-In Paste Translucent 1.5g (1.2ml), Dispensing Tip Needle Type, dispensing cover, 20x Disposable dispensing dish & 50x Disposable applicator (fine)
009542	10001339	G-CEM LinkForce Starter Kit A2 + 20x GC Automix Tip Regular, 1x G-Multi PRIMER (5ml), 1x G-Premio BOND (5ml), 20x Disposable dispensing dish, 50x Disposable applicator (fine) & Technic Card
009543	10001340	G-CEM LinkForce Starter Kit TR 1x G-CEM LinkForce Translucent 8.7g (5ml), 20x GC Automix Tip Regular, 1x G-Multi PRIMER (5ml), 1x G-Premio BOND (5ml), 20x Disposable dispensing dish, 50x Disposable applicator (fine) & Technic Card
009544	10001341	G-CEM LinkForce Cement Refill A2 8.7g/5ml
009545	10001342	G-CEM LinkForce Cement Refill TR 8.7g/5ml
009546	10001343	G-CEM LinkForce Cement Refill Opaque 8.7g/5ml
009547	10001344	G-CEM LinkForce Cement Refill Bleach 8.7g/5ml
901605	10004869	G-CEM LInkForce Refill A2 x2 + G-CEM Veneer Refill A2 Promo
901606	10004867	G-CEM LInkForce Refill A2+TR + G-CEM Veneer Refill A2 Promo