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

TF 155 05 February 2019
GMDN 35870

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

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

everX Flow

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

APPLICABLE STANDARDS

- ISO 4049: 2009 Dentistry -- Polymer-based restorative materials
- EN ISO 13485:2012 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.

everX Flow is Class IIa according to rule 5 of annex IX of the Council Directive.

Notified Body: British Standards Institution (n° 0086).

Leuven, 05 February 2019 .....

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

LIST OF PRODUCTS

Article code	Description
012898	everX Flow Syringe 2mL (3.7g) Bulk
012899	everX Flow Syringe 2mL (3.7g) Dentin
012900	everX Flow Syringe 2mL (3.7g) Bulk EEP
012901	everX Flow Syringe 2mL (3.7g) Dentin EEP