



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

TF 101 15 November 2012
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 Posterior

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 13485:2016 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.

everX Posterior is Class IIa according to rule 8 of annex IX of the Council Directive.

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

Leuven, 15/03/2021.....
Date

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





LIST OF PRODUCTS

Article code	Description
005117	everX Posterior 15 unitips
005118	everX Posterior 15 unitips EEP
005273	everX Posterior 50 Unitips
005274	everX Posterior 50 Unitips EEP
900681	everX posterior Kit 30 Unitips + Applier
900685	everX Posterior, 3 Unitips sample
900814	everX Posterior 10 Unitip Bag