



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

TF76 02      4 Oct 2010  
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 :

**Essentia® LoFlo**

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

**EN ISO 13485:2012 Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes**

**ISO 4049:2000 - Dentistry -- Polymer-based restorative materials**

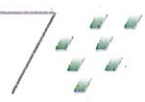
and meets the provisions of Council Directive 93/42/EEC concerning Medical Devices which apply to it, and is manufactured in accordance with the technical documentation.

This product is Class IIa according to rule 5 of annex IX of the Council Directive.

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

Leuven, .....14/02/2019.....  
Date

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



## LIST OF PRODUCTS

Article code	Description
900741	Essentia LoFlo Syringe, U, 1 x 2 mL
900742	Essentia LoFlo Syringe, U, 1 x 2 mL, EEP
901463	PROMO Essentia LoFlo 3+1