



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

TF147

09 March 2018

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

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

**Dispensing Tip Long Needle**

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

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 I (non-measuring, non-sterile) according to rule 5 of annex IX of the Council Directive.

Leuven, .....10 April 2018.....  
Date

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





## LIST OF PRODUCTS

Article code	Description
901503	Dispensing Tip Long Needle (30 pc.)

