



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

TF142 24 June 2016
GMDN 35877

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

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

GC REPAIR KIT

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.

GC REPAIR KIT is Class IIa according to rule 5 of annex IX of the Council Directive.

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

Leuven,16/04/2019.....
Date


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



LIST OF PRODUCTS

Article code	Description
901139	GC REPAIR KIT