



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

GCA0005    09 May 2006  
GMDN 35573

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

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

**COE-PAK**  
**COE-PAK AUTOMIX NDS**

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

**EN ISO 13485:2016 Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes**

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

These products are Class IIa according to rule 5 of annex IX of the Council Directive.

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

Leuven, .....12/03/21.....  
Date

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





## LIST OF PRODUCTS

Article code	New Article Code	Description
135003	10001497	COE-PAK, AUTOMIX NDS
135301	10001498	Hard & Fast
135801	10001499	Standard Pack

