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

TF109 18 July 2014
GMDN 38764

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

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

Gaenial® Flo X

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 IIa according to rule 5 of annex IX of the Council Directive.

Notified Body: British Standards Institution (n°0086).

Leuven, 18.07.2014
Date

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M. Aydin
Head Quality Assurance and Regulatory Affairs
On behalf of GC EUROPE N.V.

GC Europe Head Office
Interleuvenlaan 33
B-3001 Leuven