



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

TF#103 01 March 2013
GMDN 35876

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

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

everStick® INTRO

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

APPLICABLE STANDARDS

EN ISO 13485:2016	Medical Devices – Quality management systems – Requirements for regulatory purposes
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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.

everStick® INTRO is Class IIa according to rule 8 of annex IX of the Council Directive.

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

Leuven, 15/05/2021.....
Date

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





LIST OF PRODUCTS

Article code	New Article code	Description
900835	10003420	everStickINTRO
900854	10003437	everStickINTRO EEP