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

GCA0001 08 May 2006
GMDN 17609

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

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

GC RELINE

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

EN ISO 13485:2016 Medical devices -- Quality management systems -- Requirements for regulatory purposes

GC Company standard ADA Specification 17

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°2797).

Leuven, ...17/05/2019.....
Date

.....

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

LIST OF PRODUCTS

Article code	Description
346000	Reline Intro Package
346002	Reline powder 80g
346099	Reline Bonding Agent 15g
346191	Reline liquid 50ml