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

TF61 20 March 2007
GMDN 34771

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

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

OPTIGLAZE

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

Company specification AB-15-Q-301-429 (4)

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, ...03/02/2016.....
Date

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

LIST OF PRODUCTS

Article code	Description
002613	Optiglaze 15ml
004838	Optiglaze, bottle 15ml, EEP