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

TF 84 08 Nov. 2011
GMDN 35702

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

We ensure and declare under our sole responsibility that the product

DIAPOLISHER PASTE

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

GC Company standard AB-15-Q-301-425

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.

This product is Class I according to annex IX rule 5 of the Council Directive.

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
004415	Diapolisher paste, 1 syringe