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

TF105 25 September 2014
GMDN 45232

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

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

MI Varnish

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 The Act on Medical Devices (German Law) - transposition of Council Directive 93/42/EEC concerning Medical Devices which apply to it, and is manufactured in accordance with the technical documentation.

MI Varnish is Class IIa according to rule 8 of annex IX of the Council Directive.

Notified Body: Kiwa Cermet Italia S.p.A. (NB 0476).

Leuven, ...31/08/2016.....
Date

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

LIST OF PRODUCTS

Article code	Description
900727	MI Varnish Intro pack,10 unitdoses
900728	MI Varnish Refill pack,35 Strawberry
900729	MI Varnish Refill pack,35 Mint
900730	MI Varnish Clinic pack,100 Strawberry
900731	MI Varnish Clinic pack,100 Mint
900910	MI Varnish Sample