



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

TF105      05 December 2013  
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 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: BSI Group Deutschland GmbH (NB 0535).

Leuven, 26.09.2014  
Date

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Murat Aydin  
Quality Assurance and  
Regulatory Affairs Manager  
On behalf of GC EUROPE N.V.

