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

TF131 06 November 2018
GMDN 35866

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

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

EXACLEAR

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

APPLICABLE STANDARDS

EN ISO13485:2016	Medical Devices – Quality management systems – Requirements for regulatory purposes

and meet the provisions of Council Directive 93/42/EEC concerning Medical Devices which apply to it, and is manufactured in accordance with the technical documentation.

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

Leuven, ...18/02/2019.....
Date

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

LIST OF PRODUCTS

Article code	Description
012792	Clear Vinyl Polisiloxane, Cartridges (2x51g), Transparent
901532	Injection Modelig Kit : 1 X GUI A1, 1 X GUI A2, 1 X GUI A3 & 1 X EXACLEAR Cartridge