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

TF17 08 May 2006 GMDN 63591

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

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

PATTERN RESIN LS

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

EN ISO 13485:2016 Medical Devices - Quality Management Systems-Requirements for Regulatory Purposes

GC Company Standards AB-15-Q-301-218(2)

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° 2797).

Leuven,11/05/2021..... Date

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



LIST OF PRODUCTS

7.....

Article code	Description
335201	Pattern Resin LS 1-1 pack.
335202	Pattern Resin LS powder 100g
335203	Pattern Resin LS liquid 100g
335204	Pattern Resin LS powder 1kg
335205	Pattern Resin LS liquid 250g
890076	Pattern Resin LS Promo Pack
900494	Pattern Resin + Free Wax Promo
900407	Pattern Resin LS 1-1 pack + scale

