



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

TF48 6 August 2009
GMDN 35870

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

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

GRADIA DIRECT Flo
GRADIA DIRECT LoFlo

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

GC Company Specification: AB-15-Q-301-391 (2) (Flo)
GC Company Specification: AB-15-Q-301-392 (LoFlo)

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 family of products is Class IIa according to rule 5 of annex IX of the Council Directive.

Notified Body: British Standards Institution (n°2797)

Leuven,28/04/2019.....
Date

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



LIST OF PRODUCTS

Article code	Description
002278	Gradia Direct Flo A1 2 syringes
002279	Gradia Direct Flo A2 2 syringes
002280	Gradia Direct Flo A3 2 syringes
002281	Gradia Direct Flo A3.5 2 syringes
002284	Gradia Direct Flo AO3 2 syringes
002285	Gradia Direct Flo CV 2 syringes
002289	Gradia Direct LoFlo A1 2 syringes
002290	Gradia Direct LoFlo A2 2 syringes
002291	Gradia Direct LoFlo A3 2 syringes
002292	Gradia Direct LoFlo A3.5 2 syringes
002295	Gradia Direct LoFlo AO3 2 syringes
002296	Gradia Direct LoFlo CV 2 syringes
002298	Gradia Direct LoFlo BW 2 syringes
002358	Gradia Direct Flo BW 2 syringes
003441	Gradia Direct Flo A1 2 syringes EEP
003442	Gradia Direct Flo A2 2 syringes EEP
003443	Gradia Direct Flo A3 2 syringes EEP
003444	Gradia Direct Flo A3.5 2 syringes EEP
003445	Gradia Direct Flo AO3 2 syringes EEP
003446	Gradia Direct Flo CV 2 syringes EEP
003447	Gradia Direct Flo BW 2 syringes EEP
003448	Gradia Direct LoFlo A1 2 syringes EEP
003449	Gradia Direct LoFlo A2 2 syringes EEP
003450	Gradia Direct LoFlo A3 2 syringes EEP
003451	Gradia Direct LoFlo A3.5 2 syringes EEP
003452	Gradia Direct LoFlo AO3 2 syringes EEP
003453	Gradia Direct LoFlo CV 2 syringes EEP
003454	Gradia Direct LoFlo BW 2 syringes EEP