



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

TF48 6 August 2009

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 :

EN ISO 13485:2016 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 them, and are manufactured in accordance with the technical documentation.

This family of products is Class IIa according to rule 8 of annex IX of the Council Directive.

Notified Body: British Standards Institution (n°2797)

Leuven,09/03/2021.....
Date

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



LIST OF PRODUCTS

Article Code	New Article code	Description
002278	10000355	GRADIA Direct Flo, Syringe 2x0.8ml (1.3g), A1 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
002279	10000356	GRADIA Direct Flo, Syringe 2x0.8ml (1.3g), A2 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
002280	10000357	GRADIA Direct Flo, Syringe 2x0.8ml (1.3g), A3 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
002281	10000358	GRADIA Direct Flo, Syringe 2x0.8ml (1.3g), A3.5 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
002284	10000359	GRADIA Direct Flo, Syringe 2x0.8ml (1.3g), AO3 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
002358	10000369	GRADIA Direct Flo, Syringe 2x0.8ml (1.3g), BW + 4x Dispensing Tip (needle type), 2x Light Protective Cover
002285	10000360	GRADIA Direct Flo, Syringe 2x0.8ml (1.3g), CV + 4x Dispensing Tip (needle type), 2x Light Protective Cover
003441	10000676	GRADIA Direct Flo, Syringe 2x0.8ml (1.3g), A1 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
003442	10000677	GRADIA Direct Flo, Syringe 2x0.8ml (1.3g), A2 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
003443	10000678	GRADIA Direct Flo, Syringe 2x0.8ml (1.3g), A3 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
003444	10000679	GRADIA Direct Flo, Syringe 2x0.8ml (1.3g), A3.5 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
003445	10000680	GRADIA Direct Flo, Syringe 2x0.8ml (1.3g), AO3 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
003447	10000682	GRADIA Direct Flo, Syringe 2x0.8ml (1.3g), BW + 4x Dispensing Tip (needle type), 2x Light Protective Cover
003446	10000681	GRADIA Direct Flo, Syringe 2x0.8ml (1.3g), CV + 4x Dispensing Tip (needle type), 2x Light Protective Cover
002289	10000361	GRADIA Direct LoFlo, Syringe 2x0.8ml (1.3g), A1 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
002290	10000362	GRADIA Direct LoFlo, Syringe 2x0.8ml (1.3g), A2 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
002291	10000363	GRADIA Direct LoFlo, Syringe 2x0.8ml (1.3g), A3 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
002292	10000364	GRADIA Direct LoFlo, Syringe 2x0.8ml (1.3g), A3.5 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
002295	10000365	GRADIA Direct LoFlo, Syringe 2x0.8ml (1.3g), AO3 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
002298	10000367	GRADIA Direct LoFlo, Syringe 2x0.8ml (1.3g), BW + 4x Dispensing Tip (needle type), 2x Light Protective Cover
002296	10000366	GRADIA Direct LoFlo, Syringe 2x0.8ml (1.3g), CV + 4x Dispensing Tip (needle type), 2x Light Protective Cover
003448	10000683	GRADIA Direct LoFlo, Syringe 2x0.8ml (1.3g), A1 + 4x Dispensing Tip (needle type), 2x Light Protective Cover



003449	10000684	GRADIA Direct LoFlo, Syringe 2x0.8ml (1.3g), A2 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
003450	10000685	GRADIA Direct LoFlo, Syringe 2x0.8ml (1.3g), A3 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
003451	10000686	GRADIA Direct LoFlo, Syringe 2x0.8ml (1.3g), A3.5 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
003452	10000687	GRADIA Direct LoFlo, Syringe 2x0.8ml (1.3g), AO3 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
003454	10000689	GRADIA Direct LoFlo, Syringe 2x0.8ml (1.3g), BW + 4x Dispensing Tip (needle type), 2x Light Protective Cover
003453	10000688	GRADIA Direct LoFlo, Syringe 2x0.8ml (1.3g), CV + 4x Dispensing Tip (needle type), 2x Light Protective Cover