EU DECLARATION OF CONFORMITY
According to Annex II and Annex III of Regulation (EU) 2017/745

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

SRN: BE-MF-000001608

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

Product Name	Classification according to Annex VIII of the Regulation (EU) 2017/745	Article List	Basic UDI-DI
Exaclear	Class I, Rule 5	According to the Attachment	++J022MD0028K8

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

and meets the provisions of Regulation (EU) 2017/745 concerning Medical Devices which apply to it, and is manufactured in accordance with the technical documentation.

Leuven, 07 May 2021
Date

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

LIST OF PRODUCTS

Basic UDI-DI	Article Code	New Article code	Description
++J022MD0028K8	12792	10001483	EXACLEAR cartridges 2x 48ml (51g)