



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

TF 119 13 April 2015

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

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

Essentia

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

ISO 4049: 2019 Dentistry - Polymer-based restorative materials

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

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 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
900981	10003533	Essentia Modifier Kit 3 Syringes 2.4ml: RBM, BM, WM, 1 Syringe 2ml: OM
900991	10003543	Essentia Starter Kit Unitip 5 unitips each in 6 shades: LD, MD, DD, LE, DE, U + 1 Syringe ML + 20 Dispensing Tips III Plastic + Essentia shade guide holder & shade guide mold
900963	10003517	Essentia Starter Kit Syringe 7 Syringes (2ml), 1 of each shade: LD, MD, DD, LE, DE, U, ml, 20 Dispensing Tips III Plastic, Essentia shade guide holder, Essentia shade guide mold
900984	10003536	Essentia, Syringe 2.4ml (2.5g), BM
900986	10003538	Essentia, Syringe 2.4ml (2.5g), OM
900983	10003535	Essentia, Syringe 2.4ml (2.5g), RBM
900985	10003537	Essentia, Syringe 2.4ml (2.5g), WM
900967	10003521	Essentia, Syringe 2ml (3.4g), DD
900965	10003519	Essentia, Syringe 2ml (3.4g), LD
900966	10003520	Essentia, Syringe 2ml (3.4g), MD
900971	10003525	Essentia, Syringe 2ml (3.4g), ML
900969	10003523	Essentia, Syringe 2ml (3.8g), DE
900968	10003522	Essentia, Syringe 2ml (3.8g), LE
900970	10003524	Essentia, Syringe 2ml (4.0g), U
900995	10003546	Essentia, Unitip 15x0.16ml (0.27g), DD
900993	10003544	Essentia, Unitip 15x0.16ml (0.27g), LD
900994	10003545	Essentia, Unitip 15x0.16ml (0.27g), MD
900997	10003548	Essentia, Unitip 15x0.16ml (0.30g), DE
900996	10003547	Essentia, Unitip 15x0.16ml (0.30g), LE
900998	10003549	Essentia, Unitip 15x0.16ml (0.32g), U
900982	10003534	Essentia Modifier Kit 3 Syringes 2.4ml: RBM, BM, WM, 1 Syringe 2ml: OM
900964	10003518	Essentia Starter Kit Syringe 7 Syringes (2ml), 1 of each shade: LD, MD, DD, LE, DE, U, ml, 20 Dispensing Tips III Plastic, Essentia shade guide holder, Essentia shade guide mold
900988	10003540	Essentia, Syringe 2.4ml (2.5g), BM
900990	10003542	Essentia, Syringe 2.4ml (2.5g), OM
900987	10003539	Essentia, Syringe 2.4ml (2.5g), RBM
900989	10003541	Essentia, Syringe 2.4ml (2.5g), WM
900974	10003528	Essentia, Syringe 2ml (3.4g), DD



900972	10003526	Essentia, Syringe 2ml (3.4g), LD
900973	10003527	Essentia, Syringe 2ml (3.4g), MD
900978	10003532	Essentia, Syringe 2ml (3.4g), ML
900976	10003530	Essentia, Syringe 2ml (3.8g), DE
900975	10003529	Essentia, Syringe 2ml (3.8g), LE
900977	10003531	Essentia, Syringe 2ml (4.0g), U
901020	10003555	Essentia Sample 8 unitips EN-DE-PL
901022	10003557	Essentia Sample 8 unitips ES-IT-FR
900738	10003382	Essentia Sample 6 unitips EN-ES-DE
901420	10003382	Essentia Syringe + G-Premio BOND Promo Pack
901421	10003658	Essentia Unitip + G-Premio BOND Promo Pack
890400	10003253	Essentia Universal Kit
900753	10003396	Essentia Universal Kit Unitip
901464	10003696	PROMO Essentia U syringe 3+1
901465	10003697	PROMO Essentia U unitip 3+1
901619	10004812	SAMPLE Essentia Universal 3 unitips