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

TF119 13 April 2015
GMDN 38764

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 :

Company Specification: AB-15-Q-306-643

ISO 4049: 2009 Dentistry – Polymer-based restorative materials

ISO 7405: 2008 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry

ISO 10993-1: 2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

EN ISO 13485:2012 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.

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

Notified Body: British Standards Institution (n° 0086).

Leuven, 13.04.2015
Date

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M. Aydin
Head Quality Assurance and
Regulatory Affairs
On behalf of GC EUROPE N.V.

LIST OF PRODUCTS

Art. Nr.	Description
900963	**Essentia Starter Kit Syringe** 7 syringes, 1 of each shade: LD; MD; DD; LE; DE; U; ML 20 Dispensing Tips III Plastic
900991	**Essentia Starter Kit Unitip** 30 unitips (5 unitips each in 6 shades: LD; MD; DD; LE; DE; U) 1 syringe ML; 20 Dispensing Tips III Plastic
900981	**Essentia Modifier Kit** 4 Syringes: RBM, BM, WM, OM
900965	Essentia Syringe LD, 1 x 2 mL
900966	Essentia Syringe MD, 1 x 2 mL
900967	Essentia Syringe DD, 1 x 2 mL
900968	Essentia Syringe LE, 1 x 2 mL
900969	Essentia Syringe DE, 1 x 2 mL
900970	Essentia Syringe U, 1 x 2 mL
900971	Essentia Syringe ML, 1 x 2mL; 20 Dispensing Tips III Plastic
900993	Essentia Unitip LD, 15 x 0.16 mL
900994	Essentia Unitip MD, 15 x 0.16 mL
900995	Essentia Unitip DD, 15 x 0.16 mL
900996	Essentia Unitip LE, 15 x 0.16 mL
900997	Essentia Unitip DE, 15 x 0.16 mL
900998	Essentia Unitip U, 15 x 0.16 mL
900983	Essentia Modifier Syringe RBM, 1 x 2.4 mL
900984	Essentia Modifier Syringe BM, 1 x 2.4 mL
900985	Essentia Modifier Syringe WM, 1 x 2.4 mL
900986	Essentia Modifier Syringe OM, 1 x 2 mL
900964	**Essentia Starter Kit Syringe, EEP** 7 syringes, 1 of each shade: LD; MD; DD; LE; DE; U; ML 20 Dispensing Tips III Plastic
900982	**Essentia Modifier Kit, EEP** 4 Syringes: RBM, BM, WM, OM
900972	Essentia Syringe LD, 1 x 2 mL, EEP
900973	Essentia Syringe MD, 1 x 2 mL, EEP
900974	Essentia Syringe DD, 1 x 2 mL, EEP
900975	Essentia Syringe LE, 1 x 2 mL, EEP
900976	Essentia Syringe DE, 1 x 2 mL, EEP
900977	Essentia Syringe U, 1 x 2 mL, EEP
900978	Essentia Syringe ML, 1 x 2 mL; 20 Dispensing Tips III Plastic, EEP
900987	Essentia Modifier Syringe RBM, 1 x 2.4 mL, EEP
900988	Essentia Modifier Syringe BM, 1 x 2.4 mL, EEP
900989	Essentia Modifier Syringe WM, 1 x 2.4 mL, EEP
900990	Essentia Modifier Syringe OM, 1 x 2 mL, EEP