

The following products conform to
EC DECLARATIONS OF CONFORMITY
*(according to annex II or VII of the Council Directive 93/42/EEC
concerning medical devices)*

Name of product	Class	GMDN
Alpha-Fil	IIa	16704
Alphaplast	IIa	35875
Alpha-Silver	IIa	16704
Alpha-Silver P/L	IIa	16704
Constic	IIa	34785
Contax (Primer; Bond; Activator)	IIa	34782
Contax – Intro Kit	IIa	34782
Delta Fil	IIa	16704
Delta Fil Conditioner	IIa	42483
Dry Coat	IIa	34771
Ecusit – Composite	IIa	35875
Ecusit - Composite Repair	IIa	35875
Ecusit – Primer Mono	IIa	35875
Ecusit - Set	IIa	35875
Ecusit – Starter System	IIa	35875
Ecusit – System	IIa	35875
EcuSphere	IIa	35875
EcuSphere Starter Kit	IIa	35875
EcuSphere – Carat (Shades: A1; A2; A3; A3.5; A4; B2; B3; C3; D3)	IIa	35875
EcuSphere – Shine (Shades: A2; A3; Transparent)	IIa	35875
EcuSphere Flow	IIa	35875
EcuSphere Shape	IIa	35875
Ecosite Bulk Fill	IIa	35870
Ecosite Bond	IIa	34782
Ecosite Elements	IIa	35870
Etching Gel	IIa	36153
Flairesse Varnish	IIa	35698
Icon	IIa	35875; 36153
Ionosit - Baseline	IIa	35875
Ionosit Microspand	IIa	35875
LuxaBond Universal	IIa	34782
LuxaCam PEEK	IIa	58288
LuxaCam Composite	IIa	58288
LuxaCam PMMA	IIa	58288
LuxaCam Zirkon	IIa	62817
LuxaBond Total Etch (Bond A; Bond B; Pre-Bond)	IIa	34782
LuxaCore - Automix	IIa	38789
LuxaCore – Automix Dual	IIa	38789
LuxaCore – Smartmix Dual (Shades: light opaque, A3, blue)	IIa	38789

Name of product	Class	GMDN
LuxaCore Z - Dual	IIa	38789
LuxaCore Z Post-System	IIa	38789
LuxaCrown	IIa	16723
LuxaFlow	IIa	35875
LuxaFlow Fluorescence	IIa	35875
LuxaFlow Star	IIa	35875
LuxaFlow Ultra	IIa	35875
LuxaGlaze	IIa	31783
LuxaPick - up	IIa	17609
LuxaPost Post	IIa	38609
LuxaPost Drill	IIa	38609
LuxaPrimer Universal	IIa	34782
LuxaPrint Ortho Plus	IIa	16730
Luxatemp - Automix Plus (Shades: A1; A2; A3.5; B1; Bleach Light)	IIa	31783
Luxatemp - Glaze&Bond	IIa	31783
Luxatemp - Handmix	IIa	31783
Luxatemp - Inlay	IIa	31783
Luxatemp - System	IIa	31783
Luxatemp Star	IIa	31783
Luxatemp Ultra	IIa	31783
Luxatemp Fluorescence	IIa	31783
Luxatemp Fluorescence System	IIa	31783
Multifluorid	IIa	34771
PermaCem - Automix	IIa	35870
PermaCem - Automix Dual	IIa	35870
PermaCem - Smartmix	IIa	35870
PermaCem - Smartmix Dual	IIa	35870
PermaCem 2.0	IIa	35870
PermaCem Universal	IIa	35870
Safecap Silber 70	IIa	16367
Silane	IIa	42483
Silber 70 - Solo	IIa	16367
Solist	IIa	34782
Superlux - P/P Anterior	IIa	35875
Superlux - P/P Posterior	IIa	35875
Superlux - Universalhybrid	IIa	35875
TECO	IIa	34782
TempoCem - Automix	IIa	35870
TempoCem - Automix Soft	IIa	35870
TempoCem - Smartmix	IIa	35870
TempoCem NE - Automix	IIa	35870
TempoCem NE - Handmix	IIa	35870
TempoCem NE - Smartmix	IIa	35870
TempoCem ID	IIa	35870
Vitique (Resin cement; Catalyst; Try-In)	IIa	38645
Vitique Silane	IIa	42483

We:
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certified by
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Identification No.: 0482
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declare under our sole responsibility that the products meet the provisions of the Council Directive 93/42/EEC concerning medical devices which apply to them

I. Meyer

Regulatory Affairs Manager

20.03.2023

Date

Signature