

The following class IIa 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	35870
Alpha-Silver	IIa	16704
Alpha-Silver P/L	IIa	16704
Constic	IIa	35870
Contax (Primer; Bond; Activator)	IIa	34782
Contax – Intro Kit	IIa	34782
Dry Coat	IIa	34771
Ecosite Bulk Fill	IIa	35870
Ecosite Bond	IIa	34782
Ecusit – Composite	IIa	35870
Ecusit - Composite Repair	IIa	34782
Ecusit – Primer Mono	IIa	35870
Ecusit - Set	IIa	35870
Ecusit – Starter System	IIa	35870
Ecusit – System	IIa	35870
EcuSphere	IIa	35870
EcuSphere Starter Kit	IIa	35870
EcuSphere – Carat (Shades: A1; A2; A3; A3.5; A4; B2; B3; C3; D3)	IIa	35870
EcuSphere – Shine (Shades: A2; A3; Transparent)	IIa	35870
EcuSphere Flow	IIa	35870
EcuSphere Shape	IIa	35870
Etching Gel	IIa	36153
Flairesse Varnish	IIa	35698
Icon	IIa	35870
Ionosit - Baseline	IIa	35870
LuxaBond Total Etch (Bond A; Bond B; Pre-Bond)	IIa	34782
LuxaCam Composite	IIa	62816
LuxaCam PEEK	IIa	62816
LuxaCam PMMA	IIa	62816
LuxaCam Zirkon HT	IIa	62817
LuxaCam Zirkon HT Plus	IIa	62817
LuxaCam Zirkon LT	IIa	62817
LuxaCore - Automix	IIa	35870
LuxaCore – Automix Dual	IIa	35870
LuxaCore – Smartmix Dual (Shades: light opaque, A3, blue)	IIa	35870
LuxaCore Z - Dual	IIa	35870
LuxaCore Z Post-System	IIa	35870
LuxaCrown	IIa	35870

Name of product	Class	GMDN
LuxaFlow	IIa	35870
LuxaFlow Fluorescence	IIa	35870
LuxaFlow Star	IIa	35870
LuxaFlow Ultra	IIa	35870
LuxaPick-up	IIa	17609
LuxaPost Post	IIa	38609
LuxaPost Drill	IIa	35784
Luxatemp - Automix Plus (Shades: A1; A2; A3.5; B1; Bleach Light)	IIa	31783
Luxatemp - Glaze&Bond	IIa	45294
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
PermaCem - Automix	IIa	35870
PermaCem - Automix Dual	IIa	35870
PermaCem - Smartmix	IIa	35870
PermaCem - Smartmix Dual	IIa	35870
PermaCem 2.0	IIa	35870
Safecap Silber 70	IIa	16367
Silber 70 - Solo	IIa	16367
TECO	IIa	34782
TempoCem - Automix	IIa	62200
TempoCem - Smartmix	IIa	62200
TempoCemNE - Automix	IIa	35870
TempoCemNE - Handmix	IIa	35870
TempoCemNE - Smartmix	IIa	35870
Vitique (Resin cement; Catalyst; Try-In)	IIa	35870
Vitique Silane	IIa	34782

We:

DMG
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certified by

MEDCERT
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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

A. Nagel

CE-Officer
Hamburg, Germany

09.04.2018

Date

Signature

