

Declaration of Conformity

We, Dentalpoint AG, Bodenackerstrasse 5, CH-8957 Spreitenbach, Switzerland declare under our sole responsibility that the medical devices

ZERAMEX®T Zeralock, ZERAMEX®P6, ZERAMEX®XT and NobelPearl Tapered Implants and Abutments

Class IIb / Classification rule 8

Are in conformance with the applicable provisions of Directive 93/42/EEC and its amendments, especially with the Essential Requirements are specified in Annex I of the Directive.

Conformity assessment procedure: according to Council Directive 93/42/EEC Annex II (excluding Section 4), as documented in EC certificate number 252.971.

Applied harmonized standards are: ISO 13485:2016, ISO 10993-1:2009, EN ISO14971:2012, EN 62366:2008, EN 1641:2010, EN 1642:2012

Notified Body: NSAI
 1 Swift Square
 Dublin 9, Ireland

Identification number 0050

Certificate of Registration Number: 252.971

A compilation of the products is attached to this declaration.

Spreitenbach, 07.10.2020



Daniel Meier

Head of QM&RA

Article Number	Description	Class	Rule
XT15508	Implant ZERAMEX@XT Implant Ø 3,5x8 mm SB	IIb	8
XT15510	Implant ZERAMEX@XT Implant Ø 3,5x10 mm SB	IIb	8
XT15512	Implant ZERAMEX@XT Implant Ø 3,5x12 mm RB	IIb	8
XT16508	Implant ZERAMEX@XT Implant Ø 4,2x8 mm RB	IIb	8
XT16510	Implant ZERAMEX@XT Implant Ø 4,2x10 mm RB	IIb	8
XT16512	Implant ZERAMEX@XT Implant Ø 4,2x12 mm RB	IIb	8
XT16514	Implant ZERAMEX@XT Implant Ø 4,2x14 mm RB	IIb	8
XT17508	Implant ZERAMEX@XT Implant Ø 5,5x8 mm WB	IIb	8
XT17510	Implant ZERAMEX@XT Implant Ø 5,5x10 mm WB	IIb	8
XT17512	Implant ZERAMEX@XT Implant Ø 5,5x12 mm WB	IIb	8
SB15501	ZERAMEX@XT Abutment SB Straight, 1 mm (incl. Screw)	IIb	8
SB15502	ZERAMEX@XT Abutment SB Straight, 2 mm (incl. Screw)	IIb	8
SB15515	ZERAMEX@XT Abutment SB Angular 15°, 1 mm (incl. Screw)	IIb	8
SB15535	ZERAMEX@XT SB Zerabase X (incl. Screw)	IIb	8
SB15536	ZERAMEX@XT SB Zerabase X UNENGAGED (incl. Screw)	IIb	8
RB16501	ZERAMEX@XT Abutment RB Straight, 1 mm (incl. Screw)	IIb	8
RB16502	ZERAMEX@XT Abutment RB Straight, 2 mm (incl. Screw)	IIb	8
RB16515	ZERAMEX@XT Abutment RB Angular 15°, 1 mm (incl. Screw)	IIb	8
RB16530	ZERAMEX@XT ZERABASE RB, for crown (incl. Screw)	IIb	8
RB16531	ZERAMEX@XT ZERABASE RB, for bridge (incl. Screw)	IIb	8
RB16535	ZERAMEX@XT RB Zerabase X (incl. Screw)	IIb	8
RB16536	ZERAMEX@XT RB Zerabase X UNENGAGED (incl. Screw)	IIb	8
WB17501	ZERAMEX@XT Abutment WB Straight, 1 mm (incl. Screw)	IIb	8
WB17502	ZERAMEX@XT Abutment WB Straight, 2 mm (incl. Screw)	IIb	8
WB17515	ZERAMEX@XT Abutment WB Angular 15°, 1 mm (incl. Screw)	IIb	8
WB17530	ZERAMEX@XT ZERABASE WB, for crown (incl. Screw)	IIb	8
WB17531	ZERAMEX@XT ZERABASE WB, for bridge (incl. Screw)	IIb	8
WB17535	ZERAMEX@XT WB Zerabase X (incl. Screw)	IIb	8
WB17536	ZERAMEX@XT WB Zerabase X UNENGAGED (incl. Screw)	IIb	8
RB16550	ZERAMEX@XT VICARBO Screw RB & WB Straight & Angular	IIb	8
SB15542	ZERAMEX Docklocs® Abutment, 2mm	IIb	8
SB15543	ZERAMEX Docklocs® Abutment, 3mm	IIb	8
SB15544	ZERAMEX Docklocs® Abutment, 4mm	IIb	8