FKG
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DECLARATION OF CONFORMITY

Manufacturer:	FKG Dentaire SA Crêt-du-Locle 4 2304 La Chaux-de-Fonds Switzerland
Product:	Non-sterile instruments and accessories used in dentistry, according to attached list
Conformity Assessment:	Per MDD 93/42/EEC, Annex VII
Classification:	Class I per MDD 93/42/EEC, Annex IX, rule 1 & 5. See attached list

We declare under our sole responsibility that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for medical devices as amended by 2007/47/EC.

Notified Body:	SGS Belgium NV Noorderlaan 87 2030 Antwerpen BELGIUM Notified Body Number: 1639
Place of issue	La Chaux-de-Fonds
Date of issue :	Janaury 21st 2020
Valid until:	May 24th 2024
Signature:	FKG Dentaire SA Crêt-du-Locle 4 CH-2304 La Chaux-de-Fonds BAIZE Romain Quality & Regulatory Affairs Director

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Reference	Description	Product line	CE Class
06.030.03.010.JA	Safety Memo Disc yellow, 8 petales, unperfored	Safety Memo Disc	I
06.030.03.010.TR	Safety Memo Disc, transl., 8 petales, diam. of the hole 0.30 mm	Safety Memo Disc	I
06.030.03.100.JA	Safety Memo Disc yellow, 8 petales, unperfored	Safety Memo Disc	I
06.030.03.100.TR	Safety Memo Disc, transl., 8 petales, diam. of the hole 0.50 mm	Safety Memo Disc	I
06.030.05.010.BL	Safety Memo Disc, blue, 8 petales, diam. of the hole 0.50 mm	Safety Memo Disc	I
06.030.05.010.JA	Safety Memo Disc, yellow, 8 petales, diam. of the hole 0.50 mm	Safety Memo Disc	I
06.030.05.010.NO	Safety Memo Disc, black, 8 petales, diam. of the hole 0.50 mm	Safety Memo Disc	I
06.030.05.010.TR	Safety Memo Disc, transl., 8 petales, diam. of the hole 0.50 mm	Safety Memo Disc	I
06.030.05.100.BL	Safety Memo Disc, blue, 8 petales, diam. of the hole 0.50 mm	Safety Memo Disc	I
06.030.05.100.JA	Safety Memo Disc, yellow, 8 petales, diam. of the hole 0.50 mm	Safety Memo Disc	I
06.030.05.100.NO	Safety Memo Disc, black, 8 petales, diam. of the hole 0.50 mm	Safety Memo Disc	I
06.030.05.100.TR	Safety Memo Disc, transl., 8 petales, diam. of the hole 0.50 mm	Safety Memo Disc	I
06.030.09.010.BL	Safety Memo Disc, blue, 8 petales, diam. of the hole 0.90 mm	Safety Memo Disc	I
06.030.09.010.JA	Safety Memo Disc, yellow, 8 petales, diam. of the hole 0.90 mm	Safety Memo Disc	I
06.030.09.010.TR	Safety Memo Disc, transl., 8 petales, diam. of the hole 0.90 mm	Safety Memo Disc	I
06.030.09.051.BL	Safety Memo Disc, blue, 4 petales, diam. of the hole 0.90 mm	Safety Memo Disc	I
06.030.09.100.BL	Safety Memo Disc, blue, 8 petales, diam. of the hole 0.90 mm	Safety Memo Disc	I
06.030.09.100.JA	Safety Memo Disc, yellow, 8 petales, diam. of the hole 0.90 mm	Safety Memo Disc	I
06.030.09.100.TR	Safety Memo Disc, transl., 8 petales, diam. of the hole 0.90 mm	Safety Memo Disc	I
06.031.03.000.JA	Stop-dispenser with 100 SMD yellow without hole	SMD dispenser	
06.031.03.000.TR	Stop-dispenser with 100 SMD translucie without hole	SMD dispenser	I
06.031.05.000.BL	Stop-dispenser with 100 SMD blue, diam. of the hole 0.50 mm	SMD dispenser	I
06.031.05.000.JA	Stop-dispenser with 100 SMD yellow, diam. of the hole 0.50 mm	SMD dispenser	I
06.031.05.000.NO	Stop-dispenser with 100 SMD black, diam. of the hole 0.50 mm	SMD dispenser	I
06.031.05.000.TR	Stop-dispenser with 100 SMD translucide, diam. of the hole 0.50 mm	SMD dispenser	I
06.031.09.000.BL	Stop-dispenser with 100 SMD blue, diam. of the hole 0.90 mm	SMD dispenser	I
06.031.09.000.JA	Stop-dispenser with 100 SMD yellow, diam. of the hole 0.90 mm	SMD dispenser	I
06.031.09.000.TR	Stop-dispenser with 100 SMD translucide, diam. of the hole 0.90 mm	SMD dispenser	I
06.032.05.000.BB	SMD/R. stop-dispenser with 70 SMD blue diam. of the whole 0.50 mm and 70 rubber stop blue	SMD & Rubber Stop dispenser	I
06.032.05.000.JB	SMD/R. stop-dispenser with 70 SMD yellow diam. of the whole 0.50 mm and 70 rubber stop blue	SMD & Rubber Stop dispenser	I
06.032.05.000.JN	Stop-dispenser with 70 SMD yellow diam. of the whole 0.50 mm and 70 rubber stop black	SMD & Rubber Stop dispenser	I
06.032.05.000.NB	SMD/R. stop-dispenser with 70 SMD black diam. of the whole 0.50 mm and 70 rubber stop blue	SMD & Rubber Stop dispenser	I

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Reference	Description	Product line	CE Class
06.032.09.000.JB	Stop-dispenser with 70 SMD yellow diam. of the whole 0.90 mm and 70 rubber stop blue	SMD & Rubber Stop dispenser	I
08.096.01.000.BL	Endo-stand Easy Race, arch 12 mm, blue	Endo-stand	I
08.096.01.000.GR	Endo-stand Bio Race, arch 12 mm, grey	Endo-stand	I
08.096.01.000.NG	Endo-stand IRace, arch 12 mm, black/grey	Endo-stand	I
08.096.01.000.OR	Endo-stand Race "free style", 14 holes, arch 12 mm, orange	Endo-stand	I
08.096.01.000.RO	Endo-stand Xtrem Race, arch 12 mm, red	Endo-stand	I
08.096.01.002.GR	Endo-stand Bio Race, arch 12 mm, grey, DSD	Endo-stand	I
06.010.00.000.BL	Rubber Stops 10, unperfored, blue	Rubber Stop	I
06.010.00.000.NO	Rubber Stops 10, unperfored, black	Rubber Stop	I
06.010.00.000.RO	Rubber Stops 10, unperfored, red	Rubber Stop	I
06.010.00.000.VE	Rubber Stops 10, unperfored, green	Rubber Stop	I
06.010.00.010.BL	Rubber Stops 10, unperfored, blue	Rubber Stop	I
06.010.00.010.NO	Rubber Stops 10, unperfored, black	Rubber Stop	I
06.010.00.010.RO	Rubber Stops 10, unperfored, red	Rubber Stop	I
06.010.00.010.VE	Rubber Stops 10, unperfored, green	Rubber Stop	I
06.010.00.100.BL	Rubber Stops 10, unperfored, blue	Rubber Stop	I
06.010.00.100.JA	Rubbers Stops 10, unperfored, yellow	Rubber Stop	I
06.010.00.100.NO	Rubber Stops 10, unperfored, black	Rubber Stop	I
06.010.00.100.RO	Rubber Stops 10, unperfored, red	Rubber Stop	I
06.010.00.100.VE	Rubber Stops 10, unperfored, green	Rubber Stop	I
06.010.01.010.RO	Rubber Stops 10, perforated, red	Rubber Stop	I
06.010.01.010.VE	Rubber Stops 10, perforated, green	Rubber Stop	I
06.010.01.100.BL	Rubber Stops 10, perforated, blue	Rubber Stop	I
06.010.01.100.NO	Rubber Stops 10, perforated, black	Rubber Stop	I
06.010.01.100.RO	Rubber Stops 10, perforated, red	Rubber Stop	I
06.010.01.100.VE	Rubber Stops 10, perforated, green	Rubber Stop	I
06.010.10.100.BL	Rubber Stops 10 RC, unperfored, blue	Rubber Stop	I
06.011.00.000.BL	R. stop-dispenser with 300 rubber stop blue	Rubber Stop dispenser	I
06.011.00.000.JA	R. stop-dispenser with 300 rubber stop yellow, unperfored	Rubber Stop dispenser	I
06.011.00.000.NO	R. stop-dispenser with 300 rubber stop black, unperfored	Rubber Stop dispenser	I
06.011.00.000.RO	R. Stop-dispenser with 300 rubber stop red, unperfored	Rubber Stop dispenser	I
06.011.00.000.VE	R. stop-dispenser with 300 rubber stop green, unperfored	Rubber Stop dispenser	I
04.200.00.015.AC	Molar Matrices 200, perforated, 0.05 mm thick, steel	Matrixes	I
04.200.00.105.AC	Molar Matrices 200, perforated, 0.05 mm thick, steel	Matrixes	I
04.201.00.015.AC	Molar Matrices 201 perforated, 0.05 mm thick, steel	Matrixes	I
04.201.00.105.AC	Molar Matrices 201 perforated, 0.05 mm thick, steel	Matrixes	I
04.202.00.015.AC	Molar Matrices 202, perforated, 0.05 mm thick, steel	Matrixes	I

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Reference	Description	Product line	CE Class
04.202.00.105.AC	Molar Matrices 202, perforated, 0.05 mm thick, steel	Matrixes	I
04.203.00.015.AC	Pre-Molar Matrices 203, perforated, 0.05 mm thick, steel	Matrixes	I
04.203.00.105.AC	Pre-Molar Matrices 203, perforated, 0.05 mm thick, steel	Matrixes	I
04.204.00.015.AC	Pre-Molar Matrices 204, perforated, 0.05 mm thick, steel	Matrixes	I
04.204.00.105.AC	Pre-Molar Matrices 204, perforated, 0.05 mm thick, steel	Matrixes	I
04.205.00.015.AC	Pre-Molar Matrices 205, perforated, 0.05 mm thick, steel	Matrixes	I
04.205.00.105.AC	Pre-Molar Matrices 205, perforated, 0.05 mm thick, steel	Matrixes	I
04.206.00.013.AC	Molar Matrices 206, 0.03 mm thick, steel	Matrixes	I
04.206.00.015.AC	Molar Matrices 206, 0.05 mm thick, steel	Matrixes	I
04.206.00.015.PL	Molar Matrices 206, 0.05 mm thick, plastic	Matrixes	I
04.206.00.103.AC	Molar Matrices 206, 0.03 mm thick, steel	Matrixes	I
04.206.00.105.AC	Molar Matrices 206, 0.05 mm thick, steel	Matrixes	I
04.206.00.105.PL	Molar Matrices 206, 0.05 mm thick, plastic	Matrixes	I
04.207.00.013.AC	Molar Matrices 207, 0.03 mm thick, steel	Matrixes	I
04.207.00.015.AC	Molar Matrices 207, 0.05 mm thick, steel	Matrixes	I
04.207.00.015.PL	Molar Matrices 207, 0.05 mm thick, plastic	Matrixes	I
04.207.00.103.AC	Molar Matrices 207, 0.03 mm thick, steel	Matrixes	I
04.207.00.105.AC	Molar Matrices 207, 0.05 mm thick, steel	Matrixes	I
04.207.00.105.PL	Molar Matrices 207, 0.05 mm thick, plastic	Matrixes	I
04.208.00.013.AC	Pre-Molar Matrices 208, 0.03 mm thick, steel	Matrixes	I
04.208.00.015.AC	Pre-Molar Matrices 208, 0.05 mm thick, steel	Matrixes	I
04.208.00.015.PL	Pre-Molar Matrices 208, 0.05 mm thick, plastic	Matrixes	I
04.208.00.103.AC	Pre-Molar Matrices 208, 0.03 mm thick, steel	Matrixes	I
04.208.00.105.AC	Pre-Molar Matrices 208, 0.05 mm thick, steel	Matrixes	I
04.208.00.105.PL	Pre-Molar Matrices 208, 0.05 mm thick, plastic	Matrixes	I
04.209.00.013.AC	Pre-Molar Matrices 209, 0.03 mm thick, steel	Matrixes	I
04.209.00.015.AC	Pre-Molar Matrices 209, 0.05 mm thick, steel	Matrixes	I
04.209.00.015.PL	Pre-Molar Matrices 209, 0.05 mm thick, plastic	Matrixes	I
04.209.00.103.AC	Pre-Molar Matrices 209, 0.03 mm thick, steel	Matrixes	I
04.209.00.105.AC	Pre-Molar Matrices 209, 0.05 mm thick, steel	Matrixes	I
04.209.00.105.PL	Pre-Molar Matrices 209, 0.05 mm thick, plastic	Matrixes	I
04.210.00.013.AC	Pre-Molar Matrices 210, 0.03 mm thick, steel	Matrixes	I
04.210.00.015.AC	Pre-Molar Matrices 210, 0.05 mm thick, steel	Matrixes	I
04.210.00.015.PL	Pre-Molar Matrices 210, 0.05 mm thick, plastic	Matrixes	I
04.210.00.103.AC	Pre-Molar Matrices 210, 0.03 mm thick, steel	Matrixes	I
04.210.00.105.AC	Pre-Molar Matrices 210, 0.05 mm thick, steel	Matrixes	I
04.210.00.105.PL	Pre-Molar Matrices 210, 0.05 mm thick, plastic	Matrixes	I
04.309.00.013.AC	Molar Matrices 309, 0.03 mm thick, steel	Matrixes	I

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Reference	Description	Product line	CE Class
04.309.00.015.AC	Molar Matrices 309, 0.05 mm thick, steel	Matrixes	I
04.309.00.015.PL	Molar Matrices 309, 0.05 mm thick, plastic	Matrixes	I
04.309.00.103.AC	Molar Matrices 309, 0.03 mm thick, steel	Matrixes	I
04.309.00.105.AC	Molar Matrices 309, 0.05 mm thick, steel	Matrixes	I
04.309.00.105.PL	Molar Matrices 309, 0.05 mm thick, plastic	Matrixes	I
04.059.01.503.AC	Matrix-Bands, 1 m long, 5 mm wide, 0.03 mm thick, steel	Matrix Bands	I
04.059.01.505.AC	Matrix-Bands, 1 m long, 5 mm wide, 0.05 mm thick, steel	Matrix Bands	I
04.059.01.603.AC	Matrix-Bands, 1 m long, 6 mm wide, 0.03 mm thick, steel	Matrix Bands	I
04.059.01.605.AC	Matrix-Bands, 1 m long, 6 mm wide, 0.05 mm thick, steel	Matrix Bands	I
04.059.01.703.AC	Matrix-Bands, 1 m long, 7 mm wide, 0.03 mm thick, steel	Matrix Bands	I
04.059.01.705.AC	Matrix-Bands, 1 m long, 7 mm wide, 0.05 mm thick, steel	Matrix Bands	I
04.059.05.503.AC	Matrix-Bands, 5 m long, 5 mm wide, 0.03 mm thick, steel	Matrix Bands	I
04.059.05.505.AC	Matrix-Bands, 5 m long, 5 mm wide, 0.05 mm thick, steel	Matrix Bands	I
04.059.05.603.AC	Matrix-Bands, 5 m long, 6 mm wide, 0.03 mm thick, steel	Matrix Bands	I
04.059.05.605.AC	Matrix-Bands, 5 m long, 6 mm wide, 0.05 mm thick, steel	Matrix Bands	I
04.059.05.703.AC	Matrix-Bands, 5 m long, 7 mm wide, 0.03 mm thick, steel	Matrix Bands	I
04.059.05.705.AC	Matrix-Bands, 5 m long, 7 mm wide, 0.05 mm thick, steel	Matrix Bands	I
04.059.10.503.AC	Matrix-Bands, 10 m long, 5 mm wide, 0.03 mm thick, steel	Matrix Bands	I
04.059.10.505.AC	Matrix-Bands, 10 m long, 5 mm wide, 0.05 mm thick, steel	Matrix Bands	I
04.059.10.603.AC	Matrix-Bands, 10 m long, 6 mm wide, 0.03 mm thick, steel	Matrix Bands	I
04.059.10.605.AC	Matrix-Bands, 10 m long, 6 mm wide, 0.05 mm thick, steel	Matrix Bands	I
04.059.10.703.AC	Matrix-Bands, 10 m long, 7 mm wide, 0.03 mm thick, steel	Matrix Bands	I
04.059.10.705.AC	Matrix-Bands, 10 m long, 7 mm wide, 0.05 mm thick, teel	Matrix Bands	I
04.047.00.000.FK	Matrix-Retainers 47, FKG	Matrix Retainers	I
04.471.00.000.FK	Matrix-Retainers 471, 6 mm, i.l./s.r., steel, FKG	Matrix Retainers	I
04.472.00.000.FK	Matrix-Retainers 472, 6 mm, rect., steel, FKG	Matrix Retainers	I
04.473.00.000.FK	Matrix-Retainers 473, 6 mm, i.r./s.l., steel, FKG	Matrix Retainers	I
04.492.00.000.FK	Matrix-Retainers 492, 7 mm, rect., steel, FKG	Matrix Retainers	I
05.300.00.101.OP	Pin opaque size 1	Pins	I
05.300.00.102.OP	Pin opaque size 2	Pins	I
05.300.00.052.OP	Pin opaque size 2	Pins	I
05.300.00.101.TR	Plastic pin size 1	Pins	I
05.300.00.102.TR	Plastic pin size 2	Pins	I
05.300.00.052.TR	Plastic pin size 2	Pins	I
99.999.70.004.XX	Réglette pour rubber-stop	Ruler	I

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