



Great Lakes

DENTAL TECHNOLOGIES

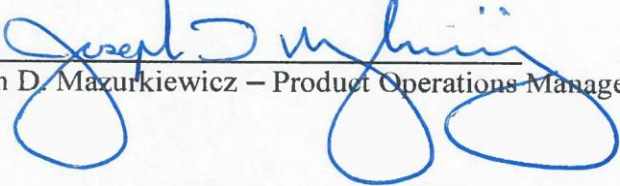
Our Vision

"Delight our customers. Respect and help our co-workers."

EC - DECLARATION OF CONFORMITY

January 20, 2021

We hereby certify that the list of Great Lakes Dental Technologies Products attached Conform to the necessary requirements set out in Annex I & IV of Regulation (EU) 2017/745 of the European Parliament and of the Council for Class I Medical devices.


Joseph D. Mazurkiewicz – Product Operations Manager

CE Declaration list as of

01/20/2021

Item	Description	Primary DI
056-050	GEORGE GAUGE	+D7750560501
056-023	GEORGE 2MM BITE FORK	+D7750560231
056-024	GEORGE 5MM BITE FORK	+D7750560241
056-025	GEORGE ASST'D BITE FORK (24PK)	+D7750560251
056-032	LONG GEORGE 2MM BITE FORK	+D7750560321
056-033	LONG GEORGE 5MM BITE FORK	+D7750560331
140-015	GL ACCULIGHT EXPANSION KEY	+D7751400151
140-020	GLO EZKEY PKG/10 *O	+D7751400201
155-028	MANDIBULAR STABLIZER-RED	+D7751550280
155-029	MANDIBULAR STABLIZER-BLUE	+D7751550290
155-100	FACE CRIB BLUE SMALL	+D7751551000

155-101	FACE CRIB BLUE MEDIUM	+D7751551010
155-102	FACE CRIB BLUE LARGE	+D7751551020
155-103	FACE CRIB PINK SMALL	+D7751551030
155-104	FACE CRIB PINK MEDIUM	+D7751551040
155-105	FACE CRIB PINK LARGE	+D7751551050
155-106	FACE CRIB PURPLE SMALL	+D7751551060
155-107	FACE CRIB PURPLE MEDIUM	+D7751551070
155-108	FACE CRIB PURPLE LARGE	+D7751551080
155-109	FACE CRIB RED SMALL	+D7751551090
155-110	FACE CRIB RED MEDIUM	+D7751551100
155-111	FACE CRIB RED LARGE	+D7751551110
155-112	FACE CRIB TAN SMAL	+D7751551120
155-113	FACE CRIB TAN MEDIUM	+D7751551130
155-114	FACE CRIB TAN LARGE	+D7751551140
155-118	LANGLADE MINI CHIN CUP	+D7751551180
155-121	PEDO-ADAPTABLE CLASS III MASK	+D7751551210
155-122	STD-ADAPTABLE CLASS III MASK	+D7751551220
155-125	GRUMMONS PROTRACTION FACE MASK	+D7751551250
155-159	VELCRO HEADCAP	+D7751551590
191-021	GLO MOUTHGUARD - PINK (DZ) *I	+D7751910211
191-022	GLO MOUTHGUARD PINK (DZ) *I	+D7751910221
191-023	GLO MOUTHGUARD PURPLE (DZ) *I	+D7751910231
191-024	GLO MOUTHGUARD PURPLE (DZ) *I	+D7751910241
191-025	GLO MOUTHGUARD ASST'D (DZ) *I	+D7751910251
191-026	GLO MOUTHGUARD BLACK (DZ) *	+D7751910261
191-027	GLO MOUTHGUARD BLACK (DZ) *	+D7751910271
255-021	CLASS 1 LUCIA JIG (12P)	+D7752550211
255-022	CLASS II LUCIA JIG (6P)	+D7752550221
255-023	CLASS 1 LUCIA JIG (24P)	+D7752550231
255-025	LUCIA JIG KIT	+D7752550251
260-031	GL SINGLE THICKNESS WAFER (25)	+D7752600311
260-032	GL - TAPERED WAFER (25)	+D7752600321

260-033	GL - 3 X 3 SHEETS (28)	+D7752600331
260-034	GL - SINGLE THICKNESS (25)	+D7752600341
260-035	GL-WAX BITE TABS (125)	+D7752600351
300-100	SP BLK VARIABLE PULLHEADCAP *O	+D7753001000
300-101	SP NAVY VARIABLE HEADCAP *O	+D7753001010
300-102	SP BROWN VARIABLE HEADPULL *O	+D7753001020
300-103	SP NAVY HI PULL HEADCAP *O	+D7753001030
300-104	5PK QUICK FIT HEAD CAP *O	+D7753001040
300-105	SP BROWN HI PULLHEADCAP *O	+D7753001050
300-106	SP NAVY HI PULL W/SLIPON *O	+D7753001060
300-107	5PK BLK HI PULL HEAD CAP *O	+D7753001070
300-121	5PR 10mm STD J HOOKS *O	+D7753001210
300-122	5PR 15mm STD J HOOKS *O	+D7753001220
300-123	5PR 10mm LONG J HOOKS *O	+D7753001230
300-125	5PR HIGH PULL STD J HOOKS *O	+D7753001250
300-126	5PR HIGH PULL LONG J HOOKS *O	+D7753001260
300-202	SP NECK PADSW/ELASTIC STRAP*O	+D7753002020
300-304	CHIN CUP SM-ORTHOPEDIC CHIN *O	+D7753003040
300-306	SM FACE MASK PROTRACTION *O	+D7753003060
300-307	LG FACE MASKPROTRACTION *O	+D7753003070
300-308	SM HICKHAM PROTRACTION *O	+D7753003080
300-309	LG HICKHAM PROTRACTION *O	+D7753003090
300-400	SM DRYFIELD KIT RED *I	+D7753004000
300-401	LG DRYFIELD KIT WHITE *I	+D7753004010
300-406	RETRACTOR - LARGE WHITE *I	+D7753004060
300-414	RETRACTOR - SMALL RED *I	+D7753004140
300-612	LARGE LIP RETRACTOR *O	+D7753006120
300-614	SMALL LIP RETRACTOR *O	+D7753006140
300-626	GL INTRAORAL MOUTH PROPS	+D7753006260
300-627	GL INTRAORAL MOUTH PROPS	+D7753006270
300-628	GL INTRAORAL MOUTH PROPS	+D7753006280
300-629	GL DOUBLE-ENDED CHEEK	+D7753006290
300-630	GL DOUBLE-ENDED CHEEK	+D7753006300
300-631	GL EXTRAORAL CHEEK RETRACTORS	+D7753006310
300-632	GL EXTRAORAL CHEEK RETRACTORS	+D7753006320

UDI Exempt

- Orthodontic Wire
- Orthodontic Clasps
- Biocryl and Mouthguard Materials
- Herbst Tubing
- Whale Tails
- Leaf Gauges
- Tongue Guards
- Low Volume Adapters