

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

DECLARATION OF CONFORMITY

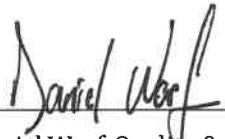
This is a declaration of conformity made under clause 6.6 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

Manufacturer's name: Great Lakes Dental Technologies
Business address: 200 Cooper Avenue, Tonawanda, NY, 14150
Medical device(s): See below for complete list of medical devices
Classification: Class I
GMDN code and term: See below for complete list of GMDN Code(s)
Scope of application: See below for complete list of lot number(s)

We hereby certify that the list of Great Lakes Dental Technologies products attached Conform to the necessary requirements set out in clause 6.6 of Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002 for Class I Medical Devices.

Standards applied: ISO 13485:2016
Therapeutic Goods (Medical Devices) Regulations 2002

Authorised signatory:



Daniel Warf, Quality & Regulatory Specialist

February 18, 2021

Date

Item	Description	Primary DI	GMDN Code
056-050	GEORGE GAUGE	+D7750560501	35850
056-023	GEORGE 2MM BITE FORK	+D7750560231	16350
056-024	GEORGE 5MM BITE FORK	+D7750560241	16350
056-025	GEORGE ASST'D BITE FORK (24PK)	+D7750560251	16350
056-032	LONG GEORGE 2MM BITE FORK	+D7750560321	16350
056-033	LONG GEORGE 5MM BITE FORK	+D7750560331	16350
140-015	GL ACCULIGHT EXPANSION KEY	+D7751400151	64768
140-020	GLO EZKEY PKG/10	+D7751400201	64768
155-028	MANDIBULAR STABLIZER-RED	+D7751550280	31757
155-029	MANDIBULAR STABLIZER-BLUE	+D7751550290	31757
155-100	FACE CRIB BLUE SMALL	+D7751551000	31757
155-101	FACE CRIB BLUE MEDIUM	+D7751551010	31757
155-102	FACE CRIB BLUE LARGE	+D7751551020	31757
155-103	FACE CRIB PINK SMALL	+D7751551030	31757
155-104	FACE CRIB PINK MEDIUM	+D7751551040	31757
155-105	FACE CRIB PINK LARGE	+D7751551050	31757
155-106	FACE CRIB PURPLE SMALL	+D7751551060	31757
155-107	FACE CRIB PURPLE MEDIUM	+D7751551070	31757
155-108	FACE CRIB PURPLE LARGE	+D7751551080	31757
155-109	FACE CRIB RED SMALL	+D7751551090	31757
155-110	FACE CRIB RED MEDIUM	+D7751551100	31757
155-111	FACE CRIB RED LARGE	+D7751551110	31757
155-112	FACE CRIB TAN SMAL	+D7751551120	31757
155-113	FACE CRIB TAN MEDIUM	+D7751551130	31757
155-114	FACE CRIB TAN LARGE	+D7751551140	31757
155-118	LANGLADE MINI CHIN CUP	+D7751551180	31757
155-121	PEDO-ADAPTABLE CLASS III MASK	+D7751551210	31757
155-122	STD-ADAPTABLE CLASS III MASK	+D7751551220	31757

155-125	GRUMMONS PROTRACTION FACE MASK	+D7751551250	31757
155-159	VELCRO HEADCAP	+D7751551590	31757
191-021	GLO MOUTHGUARD - PINK (DZ)	+D7751910211	38621
191-022	GLO MOUTHGUARD PINK (DZ)	+D7751910221	38621
191-023	GLO MOUTHGUARD PURPLE (DZ)	+D7751910231	38621
191-024	GLO MOUTHGUARD PURPLE (DZ)	+D7751910241	38621
191-025	GLO MOUTHGUARD ASST'D (DZ)	+D7751910251	38621
191-026	GLO MOUTHGUARD BLACK (DZ)	+D7751910261	38621
191-027	GLO MOUTHGUARD BLACK (DZ)	+D7751910271	38621
255-021	CLASS 1 LUCIA JIG (12P)	+D7752550211	16350
255-022	CLASS II LUCIA JIG (6P)	+D7752550221	16350
255-023	CLASS 1 LUCIA JIG (24P)	+D7752550231	16350
255-025	LUCIA JIG KIT	+D7752550251	16350
260-031	GL SINGLE THICKNESS WAFER (25)	+D7752600311	38584
260-032	GL - TAPERED WAFER (25)	+D7752600321	38584
260-033	GL - 3 X 3 SHEETS (28)	+D7752600331	38584
260-034	GL - SINGLE THICKNESS (25)	+D7752600341	38584
260-035	GL-WAX BITE TABS (125)	+D7752600351	38584
300-100	SP BLK VARIABLE PULLHEADCAP	+D7753001000	31757
300-101	SP NAVY VARIABLE HEADCAP	+D775300101 0	31757
300-102	SP BROWN VARIABLE HEADPULL	+D7753001020	31757
300-103	SP NAVY HI PULL HEADCAP	+D7753001030	31757
300-104	5PK QUICK FIT HEAD CAP	+D7753001040	31757
300-105	SP BROWN HI PULLHEADCAP	+D7753001050	31757
300-106	SP NAVY HI PULL W/SLIPON	+D7753001060	31757
300-107	5PK BLK HI PULL HEAD CAP	+D7753001070	31757
300-121	5PR 10mm STD J HOOKS	+D7753001210	31757
300-122	5PR 15mm STD J HOOKS	+D7753001220	31757
300-123	5PR 10mm LONG J HOOKS	+D7753001230	31757
300-125	5PR HIGH PULL STD J HOOKS	+D7753001250	31757

300-126	5PR HIGH PULL LONG J HOOKS	+D7753001260	31757
300-202	SP NECK PADS/ELASTIC STRAP	+D7753002020	31757
300-304	CHIN CUP SM-ORTHOPEDIC CHIN	+D7753003040	31757
300-306	SM FACE MASK PROTRACTION	+D7753003060	31757
300-307	LG FACE MASK PROTRACTION	+D7753003070	31757
300-308	SM HICKHAM PROTRACTION	+D7753003080	31757
300-309	LG HICKHAM PROTRACTION	+D7753003090	31757
300-400	SM DRYFIELD KIT RED	+D7753004000	44828
300-401	LG DRYFIELD KIT WHITE	+D7753004010	44828
300-406	RETRACTOR - LARGE WHITE	+D7753004060	44828
300-414	RETRACTOR - SMALL RED	+D7753004140	44828
300-612	LARGE LIP RETRACTOR	+D7753006120	44828
300-614	SMALL LIP RETRACTOR	+D7753006140	44828
300-626	GL INTRAORAL MOUTH PROPS	+D7753006260	44828
300-627	GL INTRAORAL MOUTH PROPS	+D7753006270	44828
300-628	GL INTRAORAL MOUTH PROPS	+D7753006280	44828
300-629	GL DOUBLE-ENDED CHEEK	+D7753006290	44828
300-630	GL DOUBLE-ENDED CHEEK	+D7753006300	44828
300-631	GL EXTRAORAL CHEEK RETRACTORS	+D7753006310	44828
300-632	GL EXTRAORAL CHEEK RETRACTORS	+D7753006320	44828