

EC DECLARATION OF CONFORMITY

According to ISO/IEC 17050-1: 2004 (Supplier's DOC) & ISO/IEC 17050-2: 2004 (Supporting Document Supplier's DOC) valid 10.05.2024

European Union
Conformité Européene

Route to Compliance: Self-Certified, Annex II & III (MDR 2017/745 for medical devices)

Device classification: Class I, invasive device with respect to the bodily orifice intended for transient use

Manufacturer: SAGA DENTAL SUPPLY AS
Øvre Langelandsvn.19
2213 Kongsvinger
Norway
Tel: +4762814898

Manufacturer SRN: NO-MF-000001425

GMDN Code: 13380

General Product Name: Lip & Cheek retractors

Intended use: Retraction and isolation of oral cavity (lip, cheek and tongue) during dental treatment.

Basic UDI-DI: ++D751retractorC4

Products:

REF	Brand Name	UDI DI	Version	
05049	COMBEE	D751050490	Large	Clear
05048	COMBEE	D751050480	Small	Clear
05047	K&K OCCLUSAL RETRACTOR	D751050470	Medium	Clear
05046	K&K OCCLUSAL RETRACTOR	D751050460	Small	Clear
05114	K&K OCCLUSAL RETRACTOR	D751051140	Medium	Clear
05113	K&K OCCLUSAL RETRACTOR	D751051130	Small	Clear

05098CL	OCCLUSAL 45 RETRACTOR	D75105098CL0	Large	Clear
05097CL	OCCLUSAL 45 RETRACTOR	D75105097CL0	Small	Clear
05098OP	OCCLUSAL 45 RETRACTOR	D75105098OP0	Large	Opaque
05097OP	OCCLUSAL 45 RETRACTOR	D75105097OP0	Small	Opaque
05073	OCCLUSAL STANDARD	D751050730	Large	Clear
05072	OCCLUSAL STANDARD	D751050720	Small	Clear
05081CL	SINGLE SIDED	D75105081CL0	Large	Clear
05080CL	SINGLE SIDED	D75105080CL0	Small	Clear
05081BLK	SINGLE SIDED	D75105081BLK0	Large	Black
05080BLK	SINGLE SIDED	D75105080BLK0	Small	Black
05064LO	LIP RING RETRACTOR	D75105064LO0	Large	Opaque
05082SO	LIP RING RETRACTOR	D75105082SO0	Small	Opaque
05065LBLU	LIP RING RETRACTOR	D75105065LBLU0	Large	Blue
05065LGRN	LIP RING RETRACTOR	D75105065LGRN0	Large	Green
05065LRED	LIP RING RETRACTOR	D75105065LRED0	Large	Red
05065LWHT	LIP RING RETRACTOR	D75105065LWHT0	Large	White
05079	ANTERIOR POSTERIOR	D751050790	NA	clear
05080	ANTERIOR POSTERIOR	D751050800	NA	black
05045	LCv2 cheek retractor	D751050450	Small	Clear
05040	LCv2 cheek retractor	D751050400	Large	Clear
05060BLU	LC RETRACTOR	D75105060BLU0	Medium	Blue
05060GRN	LC RETRACTOR	D75105060GRN0	Medium	Green
05060RED	LC RETRACTOR	D75105060RED0	Medium	Red
05060WHT	LC RETRACTOR	D75105060WHT0	Medium	White
05060YLW	LC RETRACTOR	D75105060YLW0	Medium	Yellow
05071BLU	LC RETRACTOR	D75105071BLU0	Medium	Blue
05071RED	LC RETRACTOR	D75105071RED0	Medium	Red
05059	LC RETRACTOR	D751050590	Medium	Clear
05041	LC RETRACTOR	D751050410	Small	Clear
05070	LC RETRACTOR	D751050700	Medium	Opaque
05058YLW	SCANDEE	D75105058YLW0	Large	Yellow
05057BLU	SCANDEE	D75105057BLU0	Medium	Blue
05057GRN	SCANDEE	D75105057GRN0	Medium	Green
05057RED	SCANDEE	D75105057RED0	Medium	Red
05057WHT	SCANDEE	D75105057WHT0	Medium	White
05057YLW	SCANDEE	D75105057YLW0	Medium	Yellow
05060PCWHT	SCANDEE	D75105060PCWHT0	Medium	Blue
05067GRN	SCANDEE	D75105067GRN0	Medium	Green

05067RED	SCANDEE	D75105067RED0	Medium	Red
05067WHT	SCANDEE	D75105067WHT0	Medium	White
05067YLR	SCANDEE	D75105067YLR0	Medium	Yellow
05056BLU	SCANDEE	D75105056BLU0	Small	Blue
05056RED	SCANDEE	D75105056RED0	Small	Red
05056WHT	SCANDEE	D75105056WHT0	Small	White
05077BLU	SCANDEE	D75105077BLU0	Small	Blue
05077RED	SCANDEE	D75105077RED0	Small	Red
05076	SCANDEE	D751050760	Small	Opaque
05055	SCANDEE	D751050550	Large	Clear
05054	SCANDEE	D751050540	Medium	Clear
05066	SCANDEE	D751050660	Medium	Opaque
05053	SCANDEE	D751050530	Small	Clear
05063	TCL	D751050630	Large	Clear
05075YLR	TCL	D75105075YLR0	Large	Yellow
05075BLU	TCL	D75105075BLU0	Large	Blue
05075RED	TCL	D75105075RED0	Large	Red
05075WHT	TCL	D75105075WHT0	Large	White
05075GRN	TCL	D75105075GRN0	Large	Green
05062CL	TCL	D75105062CL0	Small	Clear
05074YLR	TCL	D75105074YLR0	Small	Yellow
05074BLU	TCL	D75105074BLU0	Small	Blue
05074RED	TCL	D75105074RED0	Small	Red
05074WHT	TCL	D75105074WHT0	Small	White
05074GRN	TCL	D75105074GRN0	Small	Green
05052	MAXEE	D751050520	Large	Clear
05036	MAXEE	D751050360	Large	Black
05069	MAXEE	D751050690	Large	Opaque
05036	MAXEE	D751050360	Large	Black
05051	MAXEE	D751050510	Medium	Clear
05050	MAXEE	D751050500	Small	Clear
05068	MAXEE	D751050680	Small	Opaque
05119	K&K SHORT HANDLE	D751051190	Medium	Clear
05118	K&K SHORT HANDLE	D751051180	Small	Clear
05054-6	Scandee	D75105054-60	Medium	Clear 6pc
05057BLU-6	Scandee	D75105057BLU-60	Medium	Blue 6pc
05057RED-6	Scandee	D75105057RED-60	Medium	Red 6pc
05050-5	Maxee	D75105050-50	Small	Clear 5pc

05052-5	Maxee	D75105052-50	Large	Clear 5pc
05024	Maxee	D751050240	Pedo	w/ridges
05020	Maxee	D751050200	Small	PC Black
05056YLW	Scandee	D75105056YLW0	Small	PC Yellow
05058RED	Scandee	D75105058RED0	Large	Red
05058WHT	Scandee	D75105058WHT0	Large	White
05067BLU	Scandee	D75105067BLU0	Large	Blue
05077GRN	Scandee	D75105077GRN0	Medium	Green
05058BLU	Scandee	D75105058BLU0	Large	Blue
05025	Maxee	D751050250	Large	w/ridges
05056GRN	Scandee	D75105056GRN0	Small	Green
05034CL	Single sided	D75105034CL0	Large	Cut
05032CL	Anterior posterior	D75105032CL0	One size	Clear

This declaration of conformity is issued under the sole responsibility of Saga Dental Supply AS.

We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval to ISO 13485 issued by DNV Presafe.

All supporting documentation is retained at the premises of the manufacturer.

Signed on the behalf of Saga Dental Supply AS by

Swadesh Kumar

Dr. Swadesh Kumar BDS, D. Orth/ Managing director

Kongsvinger 08.16.2023