

Technical Sheet

Y10

BrightTonix Medical Ltd.



PRODUCT INDICATION

Product type	Dental esthetic device
Indication	Professional Teeth Whitening

PRODUCT PROPERTIES

Origin	Israel
Composition	Aqua, sorbitol, Hydrated Silica, Glycerin, sodium Hexametaphosphate, Potassium Nitrate, PEG-400, Cellulose Gum, Sodium Hydroxide, Sodium Saccharin, Sodium fluoride, Hydrolyzed Sodium Hyaluronate, Aroma, CI 42090.
Porosity	NA
Pore size	NA
Degradation kinetics	NA
Healing- / integration	NA
Storage temperature	-10°C to +55°C for Y10 system
Shelf life	36 months from production date, date is printed on the toothpaste packaging
Regulatory status	CE: Y10 system – (Low Voltage Directive); Y10 toothpaste – CE cosmetics; FDA: Y10 system – 510K exempt is initiated; Y10 toothpaste – ANDA under 505(j);
Entry on the market	The Y10 product is already available in the market since May 2017

MANUFACTURING

Production process	QOP 7110 Production planning
Packaging	Y10 system – (L×W×H) – 45 × 28 × 45 cm cardboard box; 6.5 kg
Sterilization method	NA

AVAILABLE PRODUCT LINE

Y10 products	Device contains: Machine + activation key + shade guide	FG7373x
	DSM Kits = 8 patient kits: 24 mouthpieces + 8 tubes of toothpastes	KT0003x
	Personal Kit = 1 patient kit: 3 mouthpieces + 1 tube of toothpaste	KT0007x

HOTLINE

UK: (+44) 01 296 651230
Italy: (+39) 800 810 500
Germany: (+49) 761 450 13 50

International Headquarters

Institut Straumann AG
Peter Merian-Weg 12
CH-4002 Basel, Switzerland
Phone +41 (0)61 965 11 11
Fax +41 (0)61 965 11 01
www.straumann.com