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Product Information

TheraBite®



Product description:

The Bite Pads are intended to protect the teeth when used with the TheraBite Jaw Motion Rehabilitation System. The TheraBite provides training of an anatomically correct motion of the jaw to patients experiencing mandibular hypomobility.

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Product Information

Document ID:	PF014-02-TechInfo	Edition:	08
Manufacturer:	Atos Medical AB Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden		
Classification: (EU) 2017/745	Class I, Rule 1		
Intended Use:	The TheraBite Bite Pads are self-adhesive pads intended to protect the user's teeth.		
CE Mark:	Yes, the devices are CE marked.		
GMDN code:	17802 (Jaw exerciser)		
Sterilization:	Non-sterile		
Raw material:	Foam: Polyethylene Adhesive: Polyester film, Rubber base adhesive		
Latex information:	Not manufactured with natural rubber latex		
Biological origin:	The device is not manufactured with materials derived from human or animal source.		
Handling and storage:	Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.		
Waste handling and disposal:	Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.		
Hazardous components:	None		
Expiration date:	5 years after manufacturing.		
Packaging:	The TheraBite Bite Pads includes 4 pieces of Bite Pads packed in a plastic bag made of polyethylene.		

Product Information

Devices under Basic UDI-DI: 7331791-JAW-A-000-0001-QT

REF	Name	UDI-DI
PA001	TheraBite Bite Pad, Regular (4 pcs)	07331791004834
PA002	TheraBite Bite Pad, Edentulous (4pcs)	07331791004841
PA003	TheraBite Bite Pad, Pediatric (4 pcs)	07331791004858

Atos Medical AB compatible products:

Range	BASIC UDI-DI
TheraBite Range of Motion Scale	7331791-JAW-A-000-0002-QW
TheraBite ActiveBand Kit	7331791-JAW-A-000-0000-QQ
TheraBite Jaw Motion Reh. System	7331791-JAW-0-000-0000-98