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 Atos Medical Your voice	Quality Management System
	<h2>Technical Info / Material Data Sheet</h2>

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**REF Number** TH001, TH002

**Product Name** TheraBite® Jaw Motion Rehabilitation System™

**Models:** 2 models: Regular, Pediatric

**Classification:** I (1.1 Rule 1)  
(MDD  
93/42/EEC)

**CE Mark:** Yes

**GMDN code:** 17802 (Jaw exerciser)

REF	Description	EAN code
TH001	TheraBite Jaw Motion Reh. System Adult	7331791004872
TH002	TheraBite Jaw Motion Reh. System Pediat.	7331791004889

**Produced by:** Atos Medical AB  
Kraftgatan 8  
P.O. Box 183  
242 22 Hörby  
Sweden

**Intended Use:** The TheraBite Jaw Motion Rehabilitation System is indicated for individuals who have, or are at risk of developing trismus (restrictions in their ability to open their jaw), and/or experience pain in the joints and/or muscles of the jaw. The device can also be used as a rehabilitation tool for postoperative physical therapy of the jaw, or to maintain the mouth open in a stable position, for example while performing dysphagia exercises. The TheraBite system is intended for single-patient use only.


**Description:** The Therabite Jaw Motion Rehabilitation System provides anatomically correct motion of the jaw to patients experiencing mandibular hypomobility. It includes Bite Pads which protects the teeth and Range of Motion Scale which is used to monitor the progress of the rehabilitation program.

**Sterilization:** Non-sterile product

**Raw material:** Device: Polyoxymethylene (POM), Polyamide (PA), Stainless Steel (SS)  
Bite Pads: Foam: Polyethylene  
Adhesive: Polyester film, Rubber base adhesive  
Range of Motion Scale: Coated paper

## Technical Info / Material Data Sheet

<b>Latex information:</b>	Not made with natural rubber latex.
<b>Biological origin:</b>	The device is not manufactured with any materials derived from human or animal source.
<b>Handling and storage:</b>	Keep dry and away from sunlight. Temperature limit: 2-42°C.
<b>Waste handling and disposal:</b>	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.
<b>Hazardous components:</b>	None
<b>Expiration date:</b>	≤5 years after manufacturing (depending of the expiry date of the included parts)
<b>Packaging:</b>	The TheraBite System is separately packed in a plastic bag and then in a Blue 600, Denier bag , together with two Instructions for use and one exercise log. The bag is packed in a box.

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**REF Number** PA001, PA002, PA003

**Product Name** TheraBite® Bite Pads

**Models:** 3 models: Regular, Edentulous, and Pediatric.

**Classification:** I (1.1 Rule 1)  
(MDD  
93/42/EEC)

**CE Mark:** Yes

**GMDN code:** 17802 (Jaw exerciser)

REF	Description	EAN code
PA001	TheraBite Bite Pad, Regular (4 pcs)	7331791004834
PA002	TheraBite Bite Pad, Edentulous (4pcs)	7331791004841
PA003	TheraBite Bite Pad, Pediatric (4 pcs)	7331791004858

**Produced by:** Atos Medical AB  
Kraftgatan 8  
P.O. Box 183  
242 22 Hörby  
Sweden

**Intended Use:** The TheraBite Bite Pads are self-adhesive pads intended to protect the user's teeth.

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

**Sterilization:** Non-sterile product


**Raw material:** Foam: Polyethylene  
Adhesive: Polyester film, Rubber base adhesive

**Latex information:** Not made with natural rubber latex

**Biological origin:** The device is not manufactured with any materials derived from human or animal source.

## Technical Info / Material Data Sheet

<b>Handling and storage:</b>	Keep dry and away from sunlight. Temperature limit: 2-42°C.
<b>Waste handling and disposal:</b>	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.
<b>Hazardous components:</b>	None
<b>Expiration date:</b>	5 years after manufacturing
<b>Packaging:</b>	The TheraBite Bite Pads includes 4 pieces of Bite Pads packed in a plastic bag.

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**REF Number** SC001

**Product Name** TheraBite Range of Motion Scale (150pcs)

**Models:** 1 model

**Classification:** I (1.1 Rule 1  
(MDD  
93/42/EEC)

**CE Mark:** Yes

**GMDN code:** 17802 (Jaw exerciser)

REF	Description	EAN code
SC001	TheraBite Range of Motion Scale (150pcs)	7331791004865

**Produced by:** Atos Medical AB  
Kraftgatan 8  
P.O. Box 183  
242 22 Hörby  
Sweden

**Intended Use:** The Range of Motion Scale is used to monitor the progress of the rehabilitation program.

**Description:** An area to record your progress is printed on the reverse side of the scale and an Exercise Log comes with your device to track your progress.

**Sterilization:** Non-sterile product

**Raw material:** Coated paper

**Latex information:** Not made with natural rubber latex.


**Biological origin:** The device is not manufactured with any materials derived from human or animal source.

**Handling and storage:** Keep dry and away from sunlight. Temperature limit: 2-42°C.

**Waste** Waste handling and disposal should be carried out in agreement with

**Technical Info / Material Data Sheet**

<b>handling and disposal:</b>	medical practice and applicable national laws and legislations. Used product may be a potential biohazard.
<b>Hazardous components:</b>	None
<b>Expiration date:</b>	5 years after manufacturing
<b>Packaging:</b>	The Range of Motion Scales includes 150 pcs of Scales and instructions for use packed in a re-sealable plastic bag

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**REF Number** 8260

**Product Name** TheraBite® ActiveBand™

**Models:** 1 model

**Classification:** I (1.1 Rule 1)  
(MDD  
93/42/EEC)

**CE Mark:** Yes

**GMDN code:** 17802 (Jaw exerciser)

REF	Description	EAN code
8260	TheraBite ActiveBand Kit	7331791004827

**Produced by:** Atos Medical AB  
Kraftgatan 8  
P.O. Box 183  
242 22 Hörby  
Sweden

**Intended Use:** The TheraBite ActiveBand is an elastic silicone band used together with the TheraBite Jaw Mobilizer to increase and/or maintain muscle strength and endurance of the muscles of mastication (chewing muscles). The TheraBite ActiveBand is intended for single-patient use only.

**Description:** The TheraBite ActiveBand is an unsterile elastic silicone band for single patient use. It is looped around the Lever of the TheraBite Jaw Mobilizer. The ActiveBand's position on the Load Scale determines the level of resistance.]

**Sterilization:** Non-sterile

**Raw material:** ActiveBand: Silicone  
Scale: Polypropylene (PP)

**Latex information:** Not manufactured with natural rubber latex.

**Biological origin:** The device is not manufactured with any materials derived from human or animal source.

**Handling and** Keep dry and away from sunlight. Temperature limit: 2-42°C



**Technical Info / Material Data Sheet****storage:****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:**

TheraBite ActiveBand Kit is packed separately in a plastic bag. The bag is then packed together with one instructions for use and one exercise log in a box.