DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

TheraBite Jaw Motion Rehabilitation System

Basic UDI-DI: 7331791-JAW-0-000-0000-98

This Declaration of Conformity is issued under the sole responsibility of Atos Medical AB. Atos Medical AB declares that the devices covered by the present declaration are in conformity with the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and the requirements specified herein are fulfilled and, clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002 including amendments in effect at the issuance date.

Intended use/purpose:
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.

Hörby, Sweden, date as stated on last page

.....
Henrik Heringslack, Atos Medical Site Manager
on behalf of the CEO of Atos Medical AB.

Manufacturer:	**Atos Medical AB** Kraftgatan 8, SE-242 35 Hörby Sweden	Telephone: Email: Web:	+46 (0)415 198 00 Info@atosmedical.com www.atosmedical.com
SRN number:	**SE-MF-000000725**		
Competent Authority	**Medical Products Agency** Sweden		

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

7331791-JAW-0-000-0000-98

REF	Device name	Class*	GMDN code
TH001	TheraBite Jaw Motion Rehabilitation System Adult	I	17802
TH002	TheraBite Jaw Motion Rehabilitation System Pediatric	I	17802

*Product Classification according to Annex VIII EU Medical Device Regulation 2017/745

In compliance with Therapeutic Goods (Medical Devices) Regulations 2002
Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

In compliance with UK Medical Devices Regulations 2002 as amended
Each kind of medical device to which the system has been applied fulfils the applicable obligations imposed by Annex VII and the device meets the provisions of the applicable section of the Medical Devices Regulations.

Authorized representative/UK Responsible Person:
Atos Medical UK Ltd Tottle Road
Cartwright House
Nottingham
Nottinghamshire NG2 1RT
England, United Kingdom

Common Specification(s) as per Article 9, and other Union Legislation(s)
- No relevant Common Specifications as defined in Article 9 to list.
- No relevant Union Legislations to list
- No European Representative

Document Approvals

Approved Date: 2026-01-29

Approval Task Verdict: Approve	SOFTHO Sofia Thomasson, Regulatory Affairs Professional (sofia.thomasson-atosmedical@coloplast.com) Issuer 28-Jan-2026 11:00:16 GMT+0000

Approval Task Verdict: Approve	KARNIL Karolina Nilsson, Head of RA, Voice & Respiratory Care (karolina.nilsson-atosmedical@coloplast.com) Regulatory 28-Jan-2026 19:58:22 GMT+0000

Approval Task Verdict: Approve	HENRIK.HERINGSLACK Henrik Heringslack, Site Director (henrik.heringslack-atosmedical@coloplast.com) Management 29-Jan-2026 10:40:26 GMT+0000