Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Ulrika Svensson - SEHRBHNU	2023-02-20 - 11:59
Reviewed:	QA	John Wennborg - JOHWEN	2023-02-20 - 21:11
Approved:	OP	Martin Richardson - MARRIC	2023-02-21 - 19:13
Released:	QA	Ulrika Svensson - SEHRBHNU	2023-02-22 - 08:19

This document has been electronically signed by the persons above.

Atos

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

TheraBite® Jaw Motion Rehabilitation System™

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

We, Atos Medical AB, hereby declare under our sole responsibility that the devices listed below comply with European Medical Devices Regulation (EU) 2017/745 and, any other applicable Union legislation and, clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002 and, UK 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 above

.....
Martin Richardson, Senior Vice President Operations & Quality
on behalf of the CEO of Atos Medical AB.

Manufacturer: **Atos Medical AB**
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SRN number: **SE-MF-000000725**

Competent Authority **Medical Products Agency**
Sweden

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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

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

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