Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Ulrika Svensson - SEHRBHNU	2023-05-03 - 16:08
Reviewed:	QA	John Wennborg - JOHWEN	2023-05-04 - 17:49
Approved:	OP	Martin Richardson - MARRIC	2023-05-05 - 12:45
Released:			

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

TheraBite® ActiveBand™ Kit

Basic UDI: 7331791-JAW-A-000-0000-QQ

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 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.

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**
Kraftgatan 8, SE-242 35 Hörby
Sweden

Telephone: +46 (0)415 198 00
Email: Info@atosmedical.com
Web: www.atosmedical.com

SRN number: **SE-MF-000000725**

Competent Authority **Medical Products Agency**
Sweden

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

7331791-JAW-A-000-0000-QQ

REF	Device name	Class	GMDN code
8260	TheraBite ActiveBand Kit	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

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

TheraBite® Bite Pad

Basic UDI: 7331791-JAW-A-000-0001-QT

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 Bite Pads are self-adhesive pads intended to protect the user's teeth.

Hörby, Sweden, date as stated on last page

.....
Martin Richardson, Senior Vice President Operations & Quality
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		

Document Number: VV-0544757 Status: Approved Version: 4.0
Name: DoC TheraBite Bite Pad 7331791-JAW-A-000-0001-QT

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

7331791-JAW-A-000-0001-QT

REF	Device name	Class*	GMDN code
PA001	TheraBite Bite Pad, Regular (4 pcs)	I	17802
PA002	TheraBite Bite Pad, Edentulous (4pcs)	I	17802
PA003	TheraBite Bite Pad, Pediatric (4 pcs)	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
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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: 2024-03-18

Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Quality Assurance Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 18-Mar-2024 13:49:52 GMT+0000

Approval Task Verdict: Approve	KARNIL Karolina Nilsson, Head of Regulatory Affairs (karolina.nilsson-atosmedical@coloplast.com) Regulatory 18-Mar-2024 13:52:23 GMT+0000

Approval Task Verdict: Approve	MARRIC Martin Richardson, VP, International Manufacturing, Sweden, Germany & China (martin.richardson-atosmedical@coloplast.com) Management 18-Mar-2024 14:33:03 GMT+0000

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

TheraBite® Jaw Motion Rehabilitation System™

Basic UDI: 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

.....
Martin Richardson, Senior Vice President Operations & Quality
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
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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: 2024-03-18

Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Quality Assurance Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 18-Mar-2024 13:49:39 GMT+0000

Approval Task Verdict: Approve	KARNIL Karolina Nilsson, Head of Regulatory Affairs (karolina.nilsson-atosmedical@coloplast.com) Regulatory 18-Mar-2024 13:50:30 GMT+0000

Approval Task Verdict: Approve	MARRIC Martin Richardson, VP, International Manufacturing, Sweden, Germany & China (martin.richardson-atosmedical@coloplast.com) Management 18-Mar-2024 14:33:34 GMT+0000

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

TheraBite® Range of Motion Scale

Basic UDI: 7331791-JAW-A-000-0002-QW

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 Range of Motion Scale is used to monitor the progress of the rehabilitation program.

Hörby, Sweden, date as stated on last page

.....
Martin Richardson, Senior Vice President Operations & Quality
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-A-000-0002-QW

REF	Device name	Class*	GMDN code
SC001	TheraBite Range of Motion Scale	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
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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: 2024-03-14

Approval Task Verdict: Approve	SEHRBPNH Håkan Persson, Quality Manager (hakan.persson-atosmedical@coloplast.com) Quality 13-Mar-2024 14:05:11 GMT+0000

Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Quality Assurance Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 14-Mar-2024 06:32:28 GMT+0000

Approval Task Verdict: Approve	MARRIC Martin Richardson, VP, International Manufacturing, Sweden, Germany & China (martin.richardson-atosmedical@coloplast.com) Management 14-Mar-2024 07:22:56 GMT+0000