Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Ulrika Svensson - SEHRBHNU	2021-05-19 - 09:19
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Released:	QA	Ulrika Svensson - SEHRBHNU	2021-05-19 - 17:02

This document has been electronically signed by the persons above.

Atos

DECLARATION OF CONFORMITY

TheraBite® ActiveBand™ Kit

Basic UDI: 7331791-JAW-A-000-000-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 clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002.

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: SE-MF-000000725
Atos Medical AB, Kraftgatan 8, SE-242 35 Hörby, Sweden
Tel: +46 (0)415 198 00
Email: info@atosmedical.com, Web: www.atosmedical.com

Competent Authority:
Medical Products Agency, Sweden

Document No: 10000045958 Edition: 01 Release date: 2021-05-19

DECLARATION OF CONFORMITY

7331791-JAW-A-000-000-QQ

REF	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.

For standards applied and valid conformity assessment certificates please contact the manufacturer.

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
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This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY

TheraBite® Bite Pad

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

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 clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002.

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

Hörby, Sweden date as stated above

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

Manufacturer: SE-MF-000000725
Atos Medical AB, Kraftgatan 8, SE-242 35 Hörby, Sweden
Tel: +46 (0)415 198 00
Email: info@atosmedical.com, Web: www.atosmedical.com

Competent Authority:
Medical Products Agency, Sweden

Released
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DECLARATION OF CONFORMITY

7331791-JAW-A-000-0001-QT

REF	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

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.

For standards applied and valid conformity assessment certificates please contact the manufacturer.

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
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Atos

DECLARATION OF CONFORMITY

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 clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002.

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: SE-MF-000000725
Atos Medical AB, Kraftgatan 8, SE-242 35 Hörby, Sweden
Tel: +46 (0)415 198 00
Email: info@atosmedical.com, Web: www.atosmedical.com

Competent Authority:
Medical Products Agency, Sweden

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Released

DECLARATION OF CONFORMITY

7331791-JAW-0-000-0000-98

REF	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.

For standards applied and valid conformity assessment certificates please contact the manufacturer.

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
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Released:	QA	Ulrika Svensson - SEHRBHNU	2021-05-19 - 17:03

This document has been electronically signed by the persons above.

Atos

DECLARATION OF CONFORMITY

TheraBite® Range of Motion Scale

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

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 clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002.

Intended use/purpose:
The Range of Motion Scale is used to monitor the progress of the rehabilitation program.

Hörby, Sweden date as stated above

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

Manufacturer: SE-MF-000000725
Atos Medical AB, Kraftgatan 8, SE-242 35 Hörby, Sweden
Tel: +46 (0)415 198 00
Email: info@atosmedical.com, Web: www.atosmedical.com

Competent Authority:
Medical Products Agency, Sweden

DECLARATION OF CONFORMITY

7331791-JAW-A-000-0002-QW

REF	Name	Class	GMDN code
SC001	TheraBite Range of Motion Scale (150pcs)	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.

For standards applied and valid conformity assessment certificates please contact the manufacturer.