mdd Company GmbH
High Tech Disinfection and Cleaning

**Technical Datasheet**

# Bite Block

1. **Product name** — Bite Block

2. **Trade name** — Bite Block

3. **Article number**

| Article No. | Description |
|---|---|
| BB-05-30-30 | Bite Block Silver adult use without strap, opening 21,5 x 31mm |
| BB-05-30-30-T | Bite Block Silver adult use with blue texitle strap, opening 21,5 x 31mm |
| BB-05-X | Bite Block Silver adult use with bandage, opening 21,5 x 31mm |
| BB-05-30-30-R | Bite Block Silver adult use with rubber strap, opening 21,5 x 31mm |
| BB-01-85-50 | Bite Block Yellow adult use without strap, opening 23 x 34,5mm |
| BB-01-85-50-T | Bite Block Yellow adult use with white textile strap, opening 23 x 34,5mm |
| BB-01-85-50-R | Bite Block Yellow adult use with rubber strap, opening 23 x 34,5mm |
| BB-03-30-33 | Bite Block pediatric use without strap, opening 16,5 x 25mm |
| BB-03-30-33-T | Bite Block pediatric use with white textile strap, opening 16,5 x 25mm |
| BB-03-30-33-R | Bite Block pediatric use with rubber strap, opening 16,5 x 25mm |
| BB-05-30-OXY | Oxygen Bite Block without strap, opening 25 x 18mm |
| BB-05-30-OXY-T | Oxygen Bite Block with rubber strap, opening 25 x 18mm |
| BB-05-30-OXY-R | Oxygen Bite Block with white textile strap, opening 25 x 18mm |

4. **UMDNS** — 10-405

5. **EMDN** — G030804

6. **GMDN** — 34143

7. **Product plant** — mdd Company GmbH<br>Rengglochstrasse 38<br>CH-6012 Obernau

8. **Quality management system** — Acc. to EN ISO 13485:2016

9. **Notified body** — N.A.

10. **EC Authorized Representative** — EC-REP: Prolinx GmbH,<br>Address: Brehmstr. 56, 40239,<br>Duesseldorf, Germany

# Technical Datasheet

## Bite Block

**11. UK Authorized Representative**

Prolinx Global LTD
27 Old Gloucester Street,
London, UK

**12. Brand**

mdd

**13. Intended use**

The bite block is used to protect the endoscope insertion tube from being bitten by the patient. Bite blocks are available with and without retaining straps.

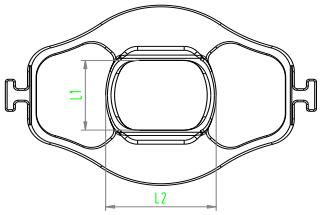
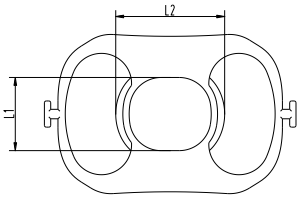
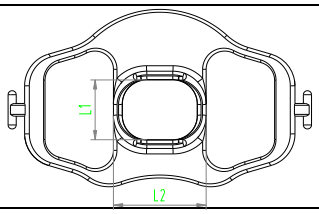
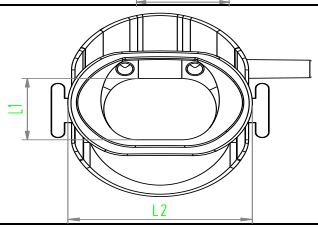
**14. Single use / reusable**

Single use

**15. Product Class acc. to MDR 2017/745**

Class I acc. Annex VIII

**16. Dimensions**

| Article No. | Model / Colour | Description | Size | Drawing |
|---|---|---|---|---|
| BB-05-30-30 | Adult / Silver | No strap | L1:21.5±3<br>L2:31±3 |  |
| BB-05-30-30-T | | With blue textile strap | | |
| BB-05-X | | With white textile strap | | |
| BB-05-30-30-R | | With green rubber strap | | |
| BB-01-85-50 | Adult / Yellow | No strap | L1:23±3<br>L2:34.5±3 |  |
| BB-01-85-50-T | | With white textile strap | | |
| BB-01-85-50-R | | With green rubber strap | | |
| BB-03-30-33 | Pediatric / Orange | No strap | L1:16.5±3<br>L2:25±3 |  |
| BB-03-30-33-T | | With blue textile strap | | |
| BB-03-30-33-R | | With green rubber strap | | |
| BB-05-30-OXY | Oxygen | No strap | L1:18±3<br>L2:40.5±3 |  |
| BB-05-30-OXY-T | | With white textile strap | | |
| BB-05-30-OXY-R | | With green rubber strap | | |

# Bite Block

**17. Material**

| Component | Generic Name |
|---|---|
| Bite Block Adult | PP |
| Bite Block Multi opening | PP |
| Bite Block Pediatric | PE |
| Bite Block Oxygen | PE |
| Bandage | Polyester + Synthetic Latex thread (Textile Strap) |
| Bandage | Rubber |

**18. Other technical details** N.A.

**19. Supplied sterile / Non-sterile** Non-sterile

**20. Packaging** 1 piece per package

**21. Special storage conditions** Store in a dry, cool, and clean place and away from direct sunlight, heat and/or chemical fumes.

**22. Shelf life** 5 years