mdd
Company GmbH
High Tech Disinfection and Cleaning

EU Declaration of Conformity
According to Art.19 of Regulation (EU) 2017/745 on Medical Devices

We, mdd Company GmbH declare under our sole responsibility that the medical device stated below meets all provisions of the Medical Device Regulation (EU)2017/745.

Name and address of the manufacturer	mdd Company GmbH Rengglochstrasse 38 6012 Obernau Switzerland
Manufacture SRN	CH-MF-000009532
Medical Device	Bite Block
Product Specifications	Refer to Attachment 1 Specification List
Basic-UDI-DI	7640170661227ZB
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.
Classification acc. to MDR Annex VIII	Class I, Rule 5
Conformity Assessment procedure	Annex I, II, III and IV of Regulation (EU) 2017/745
Notified Body (if applicable),	N/A
EC Authorized Representative	Prolinx GmbH Brehmstr. 56, 40239, Duesseldorf, Germany Tel: 0049 2131 4051968-0 Fax: 0049 2131 4051968-9 mail: med@eulinx.eu DIMDI Code: DE/0000045300
EU Representative SRN	DE-AR-000005129
This declaration is valid to:	01 May 2028

MDD Company GmbH
Rengglochstrasse 38
CH-6012 Obernau

Obernau 02 April 2025
Place, Date

Gianluca Beghetto, Managing Director
For and on behalf of mdd Company GmbH

mdd Company GmbH
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Attachment 1 Specification-List

No	Brand	Article Number	Description	Trade Name	UDI-DI					
					Primary Package		Secondary Packaging		Outer Packaging	
1	mdd	BB-05-30-30	Bite Block Adult Silver Without strap	Bite Block	1	7640170660296	100	7640170663631	400	7640170666991
2	mdd	BB-05-30-30-T	Bite Block Adult Silver With blue textile strap	Bite Block	1	7640170660401	100	7640170663747	400	7640170667103
3	mdd	BB-05-X	Bite Block Adult Silver With white textile strap	Bite Block	1	7640170663204	100	7640170666526	400	7640170669794
4	mdd	BB-05-30-30-R	Bite Block Adult Silver With rubber strap	Bite Block	1	7640170660357	100	7640170663693	400	7640170667059
5	mdd	BB-01-85-50	Bite Block Adult Yellow Without strap	Bite Block	1	7640170660265	100	7640170663600	400	7640170666960
6	mdd	BB-01-85-50-T	Bite Block Adult Yellow With white textile strap	Bite Block	1	7640170660371	100	7640170663716	400	7640170667073
7	mdd	BB-01-85-50-R	Bite Block Adult Yellow With rubber strap	Bite Block	1	7640170660326	100	7640170663662	400	7640170667028
8	mdd	BB-03-30-33	Bite Block Pediatric Orange Without strap	Bite Block	1	7640170660272	100	7640170663617	400	7640170666977
9	mdd	BB-03-30-33-T	Bite Block Pediatric Orange With white textile strap	Bite Block	1	7640170660388	100	7640170663723	400	7640170667080
10	mdd	BB-03-30-33-R	Bite Block Pediatric Orange With rubber strap	Bite Block	1	7640170660333	100	7640170663679	400	7640170667035
11	mdd	BB-05-30-OXY	Oxygen Bite Block Without strap	Bite Block	1	7640170660289	100	7640170663624	400	7640170666984
12	mdd	BB-05-30-OXY-T	Oxygen Bite Block With white textile strap	Bite Block	1	7640170660395	100	7640170663730	400	7640170667097
13	mdd	BB-05-30-OXY-R	Oxygen Bite Block With rubber strap	Bite Block	1	7640170660340	100	7640170663686	400	7640170667042