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EU DECLARATION OF CONFORMITY

BART MEDICAL S.r.l.

SRN: IT-MF-000034525

As a manufacturer, you declare under your sole responsibility that the medical devices:

Device type

THERMOPLASTIC SHEETS

Commercial name

B-FORM MOUTHGUARD

Codes, models and variants

MODEL	CODES AND VARIANTS
SQUARE 125 x 125 mm	# 1941 B-FORM MOUTHGUARD 1 color 4 mm - 12 pieces Color: Assorted
	# 1956 B-FORM MOUTHGUARD 1 color 4 mm - 12 pieces Color: Clear
	# 1957 B-FORM MOUTHGUARD 1 color 4 mm - 12 pieces Color: Orange
	# 1958 B-FORM MOUTHGUARD 1 color 4 mm - 12 pieces Color: Yellow
	# 1960 B-FORM MOUTHGUARD 1 color 4 mm - 12 pieces Color: White
	# 1961 B-FORM MOUTHGUARD 1 color 4 mm - 12 pieces Color: Green
	# 1962 B-FORM MOUTHGUARD 1 color 4 mm - 12 pieces Color: Black
	# 1963 B-FORM MOUTHGUARD 1 color 4 mm - 12 pieces Color: Red
	# 1964 B-FORM MOUTHGUARD 1 color 4 mm - 12 pieces Color: Blue
	# 1965 B-FORM MOUTHGUARD 1 color 4 mm - 12 pieces Color: Purple
	# 1967 B-FORM MOUTHGUARD 2 colors 4 mm - 12 pieces Color: Assorted
	# 1968 B-FORM MOUTHGUARD 2 colors 4 mm - 12 pieces Color: Green / Blue
	# 1969 B-FORM MOUTHGUARD 2 colors 4 mm - 12 pieces Color: Black / White
	# 1970 B-FORM MOUTHGUARD 2 colors 4 mm - 12 pieces Color: Blue / Red
# 1971 B-FORM MOUTHGUARD 2 colors 4 mm - 12 pieces Color: Black / Yellow	
# 1972 B-FORM MOUTHGUARD 2 colors 4 mm - 12 pieces Color: Black / Red	
# 1973 B-FORM MOUTHGUARD 2 colors 4 mm - 12 pieces Color: Purple / Yellow	

	<p># 1974 B-FORM MOUTHGUARD 2 colors 4 mm - 12 pieces Color: Brown / Yellow</p> <p># 1975 B-FORM MOUTHGUARD 2 colors 4 mm - 12 pieces Color: Blue / Yellow</p> <p># 1976 B-FORM MOUTHGUARD 2 colors 4 mm - 12 pieces Color: Red / White</p> <p># 1977 B-FORM MOUTHGUARD 2 colors 4 mm - 12 pieces Color: Orange / White</p> <p># 1978 B-FORM MOUTHGUARD 2 colors 4 mm - 12 pieces Color: Blue / White</p> <p># 1981 B-FORM MOUTHGUARD 2 colors 4 mm - 12 pieces Color: Black / Orange</p> <p># 1982 B-FORM MOUTHGUARD 2 colors 4 mm - 12 pieces Color: White / Purple</p> <p># 1983 B-FORM MOUTHGUARD 2 colors 4 mm - 12 pieces Color: Green / White</p> <p># 1984 B-FORM MOUTHGUARD 2 colors 4 mm - 12 pieces Color: Red / Yellow</p>
	<p># 1989 B-FORM MOUTHGUARD 3 colors 4 mm - 12 pieces Color: Assorted</p> <p># 1990 B-FORM MOUTHGUARD 3 colors 4 mm - 12 pieces Color: Green / White / Red</p> <p># 1991 B-FORM MOUTHGUARD 3 colors 4 mm - 12 pieces Color: Red / White / Blue</p> <p># 1992 B-FORM MOUTHGUARD 3 colors 4 mm - 12 pieces Color: Black / Red / White</p> <p># 1993 B-FORM MOUTHGUARD 3 colors 4 mm - 12 pieces Color: Red / White / Red</p> <p># 1994 B-FORM MOUTHGUARD 3 colors 4 mm - 12 pieces Color: Yellow / Red / Yellow</p>
ROUND Ø 120 mm	<p># 1941R B-FORM MOUTHGUARD 1 color 4 mm - 12 pieces Color: Assorted</p>
	<p># 1967R B-FORM MOUTHGUARD 2 colors 4 mm - 12 pieces Color: Assorted</p>
	<p># 1989R B-FORM MOUTHGUARD 3 colors 4 mm - 12 pieces Color: Assorted</p>
ROUND Ø 125 mm	<p># 1941T B-FORM MOUTHGUARD 1 color 4 mm - 12 pieces Color: Assorted</p>
	<p># 1967T B-FORM MOUTHGUARD 2 colors 4 mm - 12 pieces Color: Assorted</p>
	<p># 1989T B-FORM MOUTHGUARD 3 colors 4 mm - 12 pieces Color: Assorted</p>

Basic UDI-DI

805750925DISCHI04MCG

Risk class

CLASS I, in accordance with Rule 5 of Annex VIII of the MDR

are compliant with Regulation (EU) 2017/745 on Medical Devices.

Ravenna 22/03/23

CEO
