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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 GHOST ALIGNER

Codes, models and variants

MODEL	CODES AND VARIANTS
SQUARE 125 x 125 mm	# 1987 B-FORM GHOST ALIGNER 0,5 mm - 20 pieces # 1988 B-FORM GHOST ALIGNER 0,75 mm - 20 pieces # 1999 B-FORM GHOST ALIGNER 1 mm - 20 pieces
ROUND Ø 120 mm	# 1987R B-FORM GHOST ALIGNER 0,5 mm - 20 pieces # 1988R B-FORM GHOST ALIGNER 0,75 mm - 20 pieces # 1999R B-FORM GHOST ALIGNER 1 mm - 20 pieces
ROUND Ø 125 mm	# 1987T B-FORM GHOST ALIGNER 0,5 mm - 20 pieces # 1988T B-FORM GHOST ALIGNER 0,75 mm - 20 pieces # 1999T B-FORM GHOST ALIGNER 1 mm - 20 pieces

Basic UDI-DI

805750925DISCHI10GBV

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