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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 DUAL LAMINATE

Codes, models and variants

MODEL	CODES AND VARIANTS
SQUARE 125 x 125 mm	# 1943 B-FORM DUAL LAMINATE 2 mm - 12 pieces # 1939 B-FORM DUAL LAMINATE 3 mm - 12 pieces
ROUND Ø 120 mm	# 1943R B-FORM DUAL LAMINATE 2 mm - 12 pieces # 1939R B-FORM DUAL LAMINATE 3 mm - 12 pieces
ROUND Ø 125 mm	# 1943T B-FORM DUAL LAMINATE 2 mm - 12 pieces # 1939T B-FORM DUAL LAMINATE 3 mm - 12 pieces

Basic UDI-DI

805750925DISCHI09DCD

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