



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 SPLINT

Codes, models and variants

MODEL	CODES AND VARIANTS
SQUARE 125 x 125 mm	# 1828 B-FORM SPLINT 0,5 mm - 25 pieces # 1827 B-FORM SPLINT 0,8 mm - 25 pieces # 1823 B-FORM SPLINT 1 mm - 24 pieces # 1824 B-FORM SPLINT 1,5 mm - 25 pieces # 1825 B-FORM SPLINT 2 mm - 20 pieces # 1833 B-FORM SPLINT 3 mm - 20 pieces
ROUND Ø 120 mm	# 1828R B-FORM SPLINT 0,5 mm - 25 pieces # 1827R B-FORM SPLINT 0,8 mm - 25 pieces # 1823R B-FORM SPLINT 1 mm - 24 pieces # 1824R B-FORM SPLINT 1,5 mm - 25 pieces # 1825R B-FORM SPLINT 2 mm - 20 pieces # 1833R B-FORM SPLINT 3 mm - 20 pieces
ROUND Ø 125 mm	# 1828T B-FORM SPLINT 0,5 mm - 25 pieces # 1827T B-FORM SPLINT 0,8 mm - 25 pieces # 1823T B-FORM SPLINT 1 mm - 24 pieces # 1824T B-FORM SPLINT 1,5 mm - 25 pieces # 1825T B-FORM SPLINT 2 mm - 20 pieces # 1833T B-FORM SPLINT 3 mm - 20 pieces

Basic UDI-DI

805750925DISCHI02SCN

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
