EU Declaration of Conformity

Manufacturer	Boston Medical Products, Inc. 70 Chestnut Street Shrewsbury, MA 01545, USA
Authorized Representative	bess medizintechnik gmbh Gustav-Krone-Strasse 7 14167 Berlin, Germany
Medical Device	Montgomery® Safe-T-Tube™ 320006, 320007, 320008, 320009, 32006R, 32007R, 32008R, 32009R, 420010, 420011, 420012, 420013, 420014, 420015, 420016, 42010R, 42011R, 42012R, 42013R, 42014R, 42015R, 42016R, 520010, 520011, 520012, 520013, 520014, 520015, 520016, 52010R, 52011R, 52012R, 52013R, 52014R, 52015R, 52016R, 620010, 620011, 620012, 620013, 620014, 620015, 620016, 62010R, 62011R, 62012R, 62013R, 62014R, 62015R, 62016R, 721008, 721310, 71008R, 71310R
Device Classification	Class IIb Rule 8
MD Code / GMDN Code	MD 0101 / GMDN 35458
Notified Body	DQS Medizinprodukte GmbH August-Schanz-Strasse 21 60433 Frankfurt am Main, Germany, Identification Number: 0297
CE Marking First Applied	1998

Boston Medical Products, Inc. declares on its own responsibility that the above mentioned product meets the provisions of Council Directive 93/42/EEC for Medical Devices.
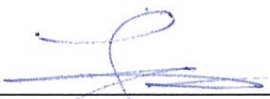
The conformity has been assessed according to Annex II excluding Section 4 of MDD 93/42/EEC (Certificate No. 170773614).

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We herewith declare that the manufacturer is exclusively responsible for issuing the declaration of conformity.

This declaration of conformity is valid until the issuing of a revised version after change of a product or until 2024-05-26, whichever occurs first.

Berlin, 2022-09-22

Heiko G. Jacobs
Director of QM / Regulatory Affairs