



Declaration of Conformity

for

Bone Marrow Needle

Product: Provided on following page(s)

Product Classification: Class IIa
Annex IX, Rule 6 of MDD 93/42/EEC

Conformity Assessment Route: Full Quality Assurance
Annex II, excluding Section 4, of MDD 93/42/EEC

EC Certificate CE Marking of Conformity Certificate No.: CE 565719

Manufacturer:	Authorized Representative:	Notified Body:
Argon Medical Devices, Inc. 1445 Flat Creek Road Athens, Texas 75751 USA	Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam Identification No.: 2797

We herewith declare under our sole responsibility that the products under this declaration are in conformity with the European Medical Devices Directive 93/42/EEC of 14 June 1993 (as amended by Directive 2007/47/EC). This declaration is based on the application of the Quality System approved for the design, manufacture and final inspection of the products concerned, in accordance with Annex II, excluding Section 4, of the Medical Devices Directive.

The conformity to the Full Quality Assurance System is described in the aforementioned EC certificate issued and delivered by BSI.

Approved By: 
Scott Bishop (Dec 22, 2022 16:06 CST)
Scott Bishop
Director of Regulatory Affairs

Dec 22, 2022
Date

THIS DECLARATION OF CONFORMITY APPLIES TO THE FOLLOWING PRODUCTS:

Product Number	Product Name
BMHN1104X	11ga x 4, B Tip, Bone Marrow Harvest Needles
BMHN1304X	13ga x 4, B Tip, Bone Marrow Harvest Needles
BMHN1302X	13ga x 2 Bone Marrow Harvest Needles
BMHN1303X	13ga x 3 Bone Marrow Harvest Needles
BMHN1104VX	11ga x 4 Bone Marrow Harvest Needles
BMHN1304VX	13ga x 4 Bone Marrow Harvest Needles
BMHN1502X	15ga x 2 Bone Marrow Harvest Needles
DBMNI1501	15ga X 2.7 Bone Marrow Aspiration Needles
DBMNI1504	15ga X 4 Bone Marrow Aspiration Needles
DBMNI1601	16ga X 2.7 Bone Marrow Aspiration Needles
DBMNJ0804TL	8ga X 4 T-Lok Bone Marrow Biopsy Needles
DBMNJ0806TL	8ga X 6 T-Lok Bone Marrow Biopsy Needles
DBMNJ1104TL	11ga X 4 T-Lok Bone Marrow Biopsy Needles
DBMNJ1104D	11ga X 4 T-Lok Bone Marrow Biopsy Needles (no needle vise)
DBMNJ1104	11ga X 4 Bone Marrow Biopsy Needles (no extraction cannula & needle vise)
DBMNJ1104R	11ga X 4 Bone Marrow Biopsy Needles (no extraction cannula)
DBMNJ1106TL	11ga X 6 T-Lok Bone Marrow Biopsy Needles
DBMNJ13025	13ga X 2.5 T-Lok Bone Marrow Biopsy Needles
DBMNJ1304	13ga X 4 T-Lok Bone Marrow Biopsy Needles
ION18015	18ga x 3.58 Pediatric Bone Marrow Needle
OBN16075	16ga X 7.5 Osty Core Bone Biopsy Needles
OBN16125	16ga X 12.5 Osty-Core Bone Biopsy Needles
OBN16165	16ga X 16.5 Osty-Core Bone Biopsy Needles
RAN-15-M	15ga X 2.7 Bone Marrow Aspiration Needles (Mermaid Medical)
RAN-154-M	15ga X 4 Bone Marrow Aspiration Needles (Mermaid Medical)

End of Product List






TF-82103 Bone Marrow Needle Rev L

Final Audit Report

2022-12-22

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