



Title: Declaration of Conformance

Author: David Howell

Revision: 5.0

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Declaration of Conformance

Bemis Suction Canisters and Suction Canister Accessories conform to the applicable Essential Requirements of EC Council Directive 93/42/EEC as amended by Directive 2007/47/EC according to Annex VII concerning Medical Devices.

Device Classification: Class I (Non-sterile, non-measuring) Rule 1

Route to Compliance: Self Certification

Standards Applied; ISO 10079-3 2014

Manufacturer/Initial Importer: Bemis Manufacturing Company, 300 Mill St. Sheboygan Falls, WI 53085 USA

Quality Management Representative: John Cutting Telephone 920-467-4621

Manufacturer: Bemis de Mexico, SA de CV, Av Texas #200, Parque Industrial Nacional, Cienega de Flores, Nuevo Leon, Mexico 65550

Divisional Quality Manager: Rodolfo Villarreal

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Authorized Representative: Bemis Limited, Loi Varley, Farrington Road, Rossendale Road Industrial Estate, Burnley Lancashire BB11 5SW, United Kingdom. Telephone 44-1282-438717

Product Type and Model Numbers and Description

Rigid Suction Canisters and Kits

006772-901 - 3000cc Hi-Flow Rigid Canister with 18" Tubing
0502-100-000 - 3000cc Hi-Flow Rigid Canister with 18" Tubing
1202DSP 050 - 1200cc Vac-U-Port Rigid Canister
1240 055 - 1200cc Hi Flow Solo Rigid Canister
2000C 025 - 2000cc Contour Canister
2002DSP 050 - 2000cc Vac-U-Port Rigid Canister
3000C 025 - 3000cc Contour Canister
3002 055 - 3000cc Hi Flow Rigid Canister
3002DSP 050 - 3000cc Vac-U-Port Rigid Canister
3025 055 - 3000cc Hi-Flow Rigid Canister with 18" Tubing
424410 - 800cc Hydrophobic Rigid Canister
434410 - 1200cc Hydrophobic Rigid Canister
435410 - 200cc Hydrophobic Rigid Canister
438410 - Hydrophobic Rigid Canister with 18" and 6' Tubing
480410 - 1200cc Hi-Flow Rigid Canister
484410 - 1200cc Hi-Flow Rigid Canister
485410 - 1200cc Hi-Flow Rigid Canister with 18" and 6' Tubing
494410 - 2000cc Hi-Flow Rigid Canister
495410 - 2000cc Hi-Flow Rigid Canister with 18" and 6' Tubing
5450-851-012 - 2000cc Hydrophobic Rigid Canister
72200024 - 3000cc Hi-Flow Rigid Canister
8002 004 - 800cc Hi-Flow Rigid Canister
8002 055 - 800cc Hi-Flow Rigid Canister
8002K 055 - Hi-Flow Rigid Canister with 6' Tubing
883001 - 1200cc Hi-Flow Rigid Canister
AQL-BEMIS - 3000cc Hi-Flow Canister with tubing & specimen adaptor
B1605 - 1200cc Hi-Flow Rigid Canister
B1605F - 1200cc Hi Flow Rigid Canister
MCANISTER1 - 800cc Hi-flow Rigid Canister



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Suction Canister Liner System

- 1500 - 1500cc Quick-Fit Outer Canister
- 1500SC - 1500cc Quick-Fit Outer Canister with Stopcock
- 1504 - 1500cc Quick-Fit Suction Liner
- 3000 - 3000cc Quick-Fit Outer Canister
- 3000SC - 3000cc Quick-Fit Outer Canister with Stopcock
- 3004 - 3000cc Quick-Fit Suction Liner

Suction Canister Accessories

- 533510 - Specimen Collection Adaptor
- 533810 - Specimen Collection Adaptor
- 535010 - Four-Canister Stopcock Manifold
- 535510 - Two-Canister Stopcock Manifold
- 536510 - 18" Non-Sterile Connecting Tubing-100 Pack
- 537010 - 18" Non-Sterile Connecting Tubing-25 Pack
- 538110 - Single Liner Manifold
- 538210 - Two-Liner Stopcock Manifold
- 538410 - Four-Liner Stopcock Manifold
- 539410 - Manifold for Stopcock Canister
- 7209824 - Specimen Collector Adapter Kit with 4 pieces of 18" Tubing
- 72203257 - Specimen Collector Adapter Kit with 1 piece of 18" Tubing

We declare that Bemis Suction Canisters and Suction Canister Accessories meet the provisions of the EC Council Directive 93/42/ECC as amended by Directive 2007/47/EC according to Annex VII concerning Medical Devices and the Essential Requirements which apply to them.

Company Representative: David P. Howell
Title: Corporate Counsel

Signature:  _____

Date: 8/1/18 _____