

EU Declaration of Conformity

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| Technical File/Design Dossier Number: 2 |
| Object of Declaration(Device Category): Admixture Products |
| Document ID: MD-SD-2005946 |
| Date of First-CE marking (acc. To MDR): N/A |
| Basic UDI-DI: N/A |

EU DECLARATION OF CONFORMITY

B. Braun Medical Inc. Allentown, PA 18109-9341
Effective Date: Last Date of Signature

| | | | |
|---|---|--|--------------------------|
| Manufacturer Address: | | Notified Body: | |
| B. Braun Medical Inc. 824 Twelfth Avenue Bethlehem, PA 18018-3524 | | TÜV SÜD Product Service GmbH [ID #0123] Ridlerstrasse 65, 80339 München Germany | |
| European Representative: | | | |
| B. Braun Melsungen AG Carl-Braun-Str. 1 34212 Melsungen Germany | | | |
| We herewith declare sole responsibility for this Declaration of Conformity and that these devices (see attached list) meet the provisions of: | | | |
| X | EC Council Directive MDD 93/42/EEC of 14 June 1993 as amended by 2007/47/EC of 5 September 2007 and Harmonized Standards indicated on the corresponding Essential Requirements Checklist. | | |
| | The devices follow the conformity assessment procedure according to Annex V of the aforementioned EC Council Directives. | | |
| | Medical Device Regulation (EU) 2017/745. | | |
| | The devices follow the conformity assessment procedure according to Annex of the aforementioned Regulation. | | |
| Supporting documentation is retained at the premises of the manufacturer. | | | |
| Authorized Persons | | | |
| Regulatory Affairs Representative: | | | |
| Name: Rebecca Stolarick | | Position: Corporate Vice President, Regulatory Affairs | Date: See Signature Page |
| Management Representative: | | | |
| Name: Nevanial Black | | Position: Director, Quality Assurance | Date: See Signature Page |

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| Technical File/Design Dossier Number: 2 |
| Object of Declaration(Device Category): Admixture Products |
| Document ID: COP-RD-8000098 |

Intended Purpose: Admixture Products are common devices used for the preparation and transfer of drug products / fluids to and from containers that are ultimately administered to the patient.

| Device: Aseptic Caps | | |
|--|--------------------------------|---|
| Classification: Class I Sterile, Rule 1 | | GMDN/EMDN: 63614 – Luer formatted protective cap |
| Item# | Description | Date Released to SAP with CE Mark |
| 418004 | Tamper-Evident Cap | 2/12/1998 |
| 418010 | Multi-Ad Luer Slip Syringe Cap | 2/6/1998 |
| 418012 | Multi-Ad Luer Lock Syringe Cap | 2/6/1998 |
| 418013 | Multi-Ad Luer Lock Syringe Cap | 2/6/1998 |
| 418017 | Replacement Cap | 6/17/1998 |
| 418200 | Flexible Syringe Cap | 2/12/1998 |
| 418202 | Flexible Syringe Cap | 2/12/1998 |
| 474900 | Replacement Cap | 4/29/1999 |

| Device: Dispensing Pins | | |
|--|---------------------------|---|
| Classification: Class I Sterile, Rule 2 | | GMDN/EMDN: 60539 – Vial / bottle adapter, non-hermetic |
| Item# | Description | Date Released to SAP with CE Mark |
| 412006 | Dispensing Pin | 1/27/98 |
| 413500 | Dispensing Pin | 7/10/00 |
| 413501 | Dispensing Pin | 1/27/98 |
| 412000 | Mini-Spike Dispensing Pin | 1/27/98 |
| 412023 | Dispensing Pin | 7/31/00 |

| Device: Dispensing Pins | | |
|--|---------------------------|---|
| Classification: Class I Sterile, Rule 2 | | GMDN/EMDN: 64996 – Luer formatted bag access spike |
| Item# | Description | Date Released to SAP with CE Mark |
| 413504 | Mini-Spike Dispensing Pin | 12/19/98 |

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| Device: Filter Devices | | |
|--|---|-----------------------------------|
| Classification: Class I Sterile, Rule 2 | GMDN/EMDN: 16266 – Medication transfer needle, filtering | |
| Item# | Description | Date Released to SAP with CE Mark |
| 415025 | Filter Needle | 4/16/1998 |
| 415030 | Filter Needle | 4/16/1998 |
| 415035 | Filter Needle | 4/16/1998 |
| 415040 | Filter Needle | 4/16/1998 |
| 415041 | High Flow Filter Needle | 6/4/1999 |
| 415042 | Filter Needle II | 3/25/1998 |
| 7L3052 | Filter Needle | 2/18/2001 |
| 415020 | Filter Straw | 4/16/1998 |
| 415021 | Filter Straw | 4/16/1998 |

| Device: Filter Devices | | |
|--|--|-----------------------------------|
| Classification: Class I Sterile, Rule 2 | GMDN/EMDN: 46817 – Syringe filter, clinical | |
| Item# | Description | Date Released to SAP with CE Mark |
| 414995 | 1.2 µm Disk Filter | 3/18/1998 |
| 415002 | 0.2 µm Disk Filter | 3/18/1998 |
| 415008 | 5 µm Disk Filter | 3/25/2004 |

| Device: Fluid Dispensing Connectors | | |
|--|---|-----------------------------------|
| Classification: Class I Sterile, Rule 2 | GMDN/EMDN: 60538-IV line syringe/ luer connector | |
| Item# | Description | Date Released to SAP with CE Mark |
| 415080 | Fluid Dispensing Connector | 5/29/1998 |
| 415081 | Fluid Dispensing Connector | 5/29/1998 |

| Device: Fluid Transfer Sets | | |
|--|--|-----------------------------------|
| Classification: Class I Sterile, Rule 2 | GMDN/EMDN: 16807-Pharmaceutical fluid-dispensing system | |
| Item# | Description | Date Released to SAP with CE Mark |
| 513548 | Multi-Ad Fluid Transfer Set | 4/20/1998 |

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| Device: Luer Adapters | | |
|--|---|-----------------------------------|
| Classification: Class I Sterile, Rule 2 | GMDN/EMDN: 60538-IV line syringe/ luer connector | |
| Item# | Description | Date Released to SAP with CE Mark |
| 418021 | Filter Hub | 4/1/98 |
| 7B3118 | Filter Hub | 12/10/10 |

| Device: Multi-Ad Systems | | |
|--|--|-----------------------------------|
| Classification: Class I Sterile, Rule 2 | GMDN/EMDN: 16807-Pharmaceutical fluid-dispensing system | |
| Item# | Description | Date Released to SAP with CE Mark |
| 513506 | Multi-Ad Fluid Dispensing system | 3/16/1998 |
| 513540 | Multi-Ad Fluid Dispensing System | 5/29/1998 |

| Device: Transfer Devices | | |
|--|---|-----------------------------------|
| Classification: Class I Sterile, Rule 2 | GMDN/EMDN: 16627-Medication transfer needle, basic | |
| Item# | Description | Date Released to SAP with CE Mark |
| 415017 | Transfer Needle, Double-Ended, Non-Filtered | 6/4/1998 |

| Device: Transfer Devices | | |
|--|---|-----------------------------------|
| Classification: Class I Sterile, Rule 2 | GMDN/EMDN: 60539 – Vial / bottle adapter, non-hermetic | |
| Item# | Description | Date Released to SAP with CE Mark |
| 412022 | Dispensing Pin | 11/23/1998 |
| 415019 | Micro Pin | 8/31/1998 |
| 412012 | Mini-Spike Dispensing Pin | 2/12/1998 |
| 7B5019 | Micro Pin | 4/4/2007 |

| Device: Transfer Devices | | |
|--|---|-----------------------------------|
| Classification: Class I Sterile, Rule 2 | GMDN/EMDN: 41222 – Medication transfer Set | |
| Item# | Description | Date Released to SAP with CE Mark |
| 412003 | Chemo Dispensing Pin S.C. | 5/18/1998 |
| 412014 | Chemo Dispensing Pin | 2/6/1998 |
| 7A5012 | Vented Transfer Device | 12/2/2005 |

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| Device: Transfer Devices | | |
|--|--|---|
| Classification: Class I Sterile, Rule 2 | | GMDN/EMDN: 64997 – Non-ISO80369 formatted bag access spike |
| Item# | Description | Date Released to SAP with CE Mark |
| 412013 | Dispensing Pin | 2/12/1998 |
| 412021 | Vented Dispensing Pin with One-Way Valve | 2/6/1998 |

| Device: Transfer Devices | | |
|--|---|---|
| Classification: Class I Sterile, Rule 2 | | GMDN/EMDN: 64998 – Double-ended bag access spike |
| Item# | Description | Date Released to SAP with CE Mark |
| 7A3814 | BSS Plus Sterile Vacuum Transfer Device | 6/11/1998 |
| 7A3261 | Dual Spike Transfer Device | 6/22/2012 |

| Device: Vented Needles | | |
|--|-----------------------------|--|
| Classification: Class I Sterile, Rule 2 | | GMDN/EMDN: 16628-Medication transfer needle, vented |
| Item# | Description | Date Released to SAP with CE Mark |
| 415070 | Vented Needle | 4/1/1998 |
| 415072 | Vented Needle, Lateral Flow | 4/1/1998 |

| Device: Dual Check Valves | | |
|--|---------------------------------|---|
| Classification: Class I Sterile, Rule 2 | | GMDN/EMDN: 32172-Intravenous line stopcock |
| Item# | Description | Date Released to SAP with CE Mark |
| 415060 | Normally Closed Backcheck Valve | 10/19/1998 |

| Device: APEX Transfer Set | | |
|--|---|--|
| Classification: Class I Sterile, Rule 2 | | GMDN/EMDN: 41646-Compounding transfer set |
| Item# | Description | Date Released to SAP with CE Mark |
| 2112650 | 26-Lead Transfer Set for use with APEX Compounding System | 10/01/2020 |

EU Declaration of Conformity**CHANGE HISTORY**

| <u>RATIONALE SUMMARY</u> | | <u>CCR#</u> | N/A |
|---|-----------------|--|---|
| Initial release of COP-RD format. Replaces MD-SD-2005946. | | | |
| <u>CHANGE SUMMARY</u> | | | |
| <u>SECTION/PAGE</u> | | <u>DESCRIPTION</u> | |
| N/A | | N/A | |
| N/A | | N/A | |
| <u>SUPPORTING DATA (Y/N)</u> | | N | <u>DOCUMENT NAME OF SUPPORTING DATA</u> |
| | | | N/A |
| N/A | | | |
| <u>ADD / DELETE KEYWORDS FOR THIS DOCUMENT (Y/N)</u> | | N | |
| <u>ADD:</u> | | N/A | |
| <u>DELETE</u> | | N/A | |
| <u>RELATED DOCUMENTS TO THIS VERSION (Y/N)</u> | | Y | |
| <u>DOCUMENT NUMBER</u> | <u>REVISION</u> | <u>TITLE</u> | |
| MD-SD-2005946 | 4 | Declaration of Conformity Technical File 2 | |

Title: Declaration of Conformity Technical File 2 Initiator: Tracy ? Larish

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

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Meaning: Document signed as Author
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Meaning: Precheck of Document
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