

EU Declaration of Conformity

Technical File/Design Dossier Number: 1
Object of Declaration(Device Category): IV Administration Devices (and Accessories)
Document ID: COP-RD-8000095
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 II, excluding 4 for Class IIa and Annex V for Class I sterile, 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: Nevaniel Black		Position: Director, Quality Assurance	
		Date: See Signature Page	

EU Declaration of Conformity

Technical File/Design Dossier Number: 1
Object of Declaration(Device Category): IV Administration Devices (and Accessories)
Document ID: COP-RD-8000095

Intended Purpose: IV Administration Devices (and Accessories) include devices that are for infusing fluids into or withdrawing fluids from the body, devices to deliver and/or aspirate fluids, including medicines and blood, and devices to disinfect other IV Administration Devices.

Device: Extensions Sets		
Classification: Class I Sterile, Rule 2	GMDN/EMDN: GMDN12170-Intravenous administration tubing extension set	
Item#	Description	Date Released to SAP with CE Mark
471950	Smallbore T-Port Extension Set	4/24/1998
471954	Smallbore T-Port Extension Set	8/30/1999
471980	Y-Extension Set	6/29/1998
471987	Smallbore T-Port Extension Set	3/10/2008
471991	Smallbore Extension Set	5/27/1998
471994	Smallbore Y-Extension Set	5/14/1998
472060	Smallbore Extension Set	8/17/1998
473012	Extension Set	2/22/2000
473045	Smallbore Extension Set	7/27/1998
473442	Smallbore Extension Set	12/14/1999
7B3240	Standard Bore Extension Set	8/27/1999

Device: Caresite/Steadycare Extension Sets		
Classification: Class IIa, Rule 2	GMDN/EMDN: GMDN 12170-Intravenous administration tubing extension set	
Item#	Description	Date Released to SAP with CE Mark
470100	Caresite® Smallbore Extension Set	5/2/2012
470100-01	Caresite® Smallbore Extension Set (export only)	4/7/2014
470106	Caresite® Y-Extension Set	5/2/2012
470106-01	Caresite® Y-Extension Set (export only)	4/16/2014
470108	Caresite® Extension Set	5/2/2012
470108-01	Caresite® Extension Set (export only)	4/7/2014
470160	Caresite® Smallbore Triple Leg Extension Set (export only)	10/30/2014
470161	Caresite® Smallbore Triple Leg Extension Set (export only)	10/30/2014
470182	Caresite® Smallbore Double Extension Set (export only)	6/18/2015
470183	Caresite® Extension Set (export only)	8/31/2015
470185	SteadyCare™ Smallbore Extension Set	7/31/2017
470186	SteadyCare™ Extension Set	7/31/2017
470187	SteadyCare™ Extension Set	7/31/2017
470188	SteadyCare™ Extension Set	7/31/2017
470193	SteadyCare™ Smallbore Extension Set	7/31/2017
470200-01	Caresite® Bifurcated Extension Set (export only)	1/30/2019

EU Declaration of Conformity

Technical File/Design Dossier Number: 1
Object of Declaration (Device Category): IV Administration Devices (and Accessories)
Document ID: COP-RD-8000095

Device: Filtered Extensions Sets		
Classification: Class I Sterile, Rule 2	GMDN/EMDN: GMDN 12170-Intravenous administration tubing extension set	
Item#	Description	Date Released to SAP with CE Mark
473989	Filtered Extension Set	9/19/2002
473994	Filtered Extension Set	2/20/2003

Device: Intermittent Injection Caps		
Classification: Class I Sterile, Rule 2	GMDN/EMDN: GMDN 63614-Luer-formatted protective cap	
Item#	Description	Date Released to SAP with CE Mark
418020	INT Stopper	6/30/1998
418030	Short, Luer Lock INT Stopper	6/11/1998

Device: Ultrasite Valve		
Classification: Class I Sterile, Rule 2	GMDN/EMDN: GMDN 42727-Positive-pressure needleless valve-connector	
Item#	Description	Date Released to SAP with CE Mark
415110	Ultrasite Injection Site	12/18/1998
415111	Ultrasite Injection Site	1/9/2004

Device: Safsite Valve		
Classification: Class I Sterile, Rule 2	GMDN/EMDN: GMDN 42743-Negative-pressure needleless valve-connector	
Item#	Description	Date Released to SAP with CE Mark
415067	Safsite® Injection Site and Cap	2/12/1998
415068	Safsite® Injection Site	2/12/1998
415069	Safsite® Injection Site with 19 Ga. X 1 in. Needle	6/5/1998

Device: Normally Closed Backcheck Valve		
Classification: Class I Sterile, Rule 2	GMDN/EMDN: GMDN 34099-In-line backflow valve, single-use	
Item#	Description	Date Released to SAP with CE Mark
415062	Normally Closed Backcheck Valve	4/24/1998

Device: Caresite Luer Access Device		
Classification: Class IIa, Rule 2	GMDN/EMDN: GMDN 42727-Positive-pressure needleless valve-connector	
Item#	Description	Date Released to SAP with CE Mark
415122	Caresite® Luer Access Device	6/23/2009
415122-01	Caresite® Luer Access Device (export only)	4/30/2014

CHANGE HISTORY

<u>RATIONALE SUMMARY</u>		<u>CCR#</u>	N/A
Initial release of COP-RD format. Replaces MD-SD-2005898. Updated Intermittent Injection Caps GMDN number to 63614 from 58977. Removed CareCap Disinfection Cap			
<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>		<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-2005898	7	Declaration of Conformity Technical File 1	

Title: Declaration of Conformity Technical File 1 Initiator: Tracy ? Larish

B. Braun Medical Inc. - Document No.: COP-RD-8000095 - Version: 1.0 - Document ID: COP-RD-8000095 - Effective Date: 2021-02-23 - Status: Effective

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

UserName: Larish, Tracy (laritrus)
Title: Sr. Regulatory Affairs Specialist
Date: Friday, 19 February 2021, 00:44 W. Europe Daylight Time
Meaning: Document signed as Author
=====

UserName: Stoliker, Michael (stolmius)
Title: Document Control Administrator
Date: Friday, 19 February 2021, 15:08 W. Europe Daylight Time
Meaning: Precheck of Document
=====

UserName: Black, Nevaniel (blacnvus)
Title: Director, Quality
Date: Monday, 22 February 2021, 21:50 W. Europe Daylight Time
Meaning: Approve Document
=====

UserName: Stolarick, Rebecca (stolreus)
Title: Corporate Vice President, Regulatory Affairs
Date: Monday, 22 February 2021, 23:10 W. Europe Daylight Time
Meaning: Approve Document
=====

UserName: Stoliker, Michael (stolmius)
Title: Document Control Administrator
Date: Tuesday, 23 February 2021, 18:03 W. Europe Daylight Time
Meaning: Final Release of the Document
=====