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

This document contains information that is the confidential and proprietary property of B. Braun. Any dissemination, distribution or copying of this document is strictly prohibited without the prior written consent of B. Braun. Anyone receiving this document in error should immediately notify B. Braun's Legal Department and return this document to B.Braun Medical Inc. Viewed by:laritrus

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

RATIONALE SUMMARY	**CCR#**	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		

CHANGE SUMMARY	
SECTION/PAGE	**DESCRIPTION**
N/A	N/A
N/A	N/A

SUPPORTING DATA (Y/N)	N	**DOCUMENT NAME OF SUPPORTING DATA**	N/A
N/A			

ADD / DELETE KEYWORDS FOR THIS DOCUMENT (Y/N)	N
ADD:	N/A
DELETE	N/A

RELATED DOCUMENTS TO THIS VERSION (Y/N)		Y
DOCUMENT NUMBER	**REVISION**	**TITLE**
MD-SD-2005898	7	Declaration of Conformity Technical File 1

Document No.: COP-RD-8000095 - Version: 1.0 - Document ID: COP-RD-8000095, Date/Time Printed/Viewed: 2023-12-22, 15:18 (CET)

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

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
==========