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DECLARATION OF CONFORMITY Medical Devices

We hereby declare that the distributed **CE** marked products, specified in the Annexed product list, conform to the product(s) covered by the "EC Certificate – Production Quality Assurance" Certificate No. **CE 616021**, first issued on **11AUG2016** and delivered by B.S.I, Notified Body Identification Number 2797, in accordance with Annex V for Class IIa sterile products, as defined in the Council Directive 93/42/EEC of 14 June 1993 and as amended by Directive 2007/47/EC of 5 September 2007.

This declaration is supported by the ISO 13485:2003 & EN ISO 13485:2012 Quality System Certification, MD 63661, issued by B.S.I. Group America.

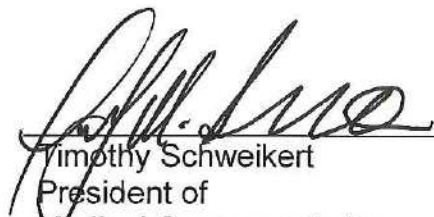
EU Authorized Representative:
MPS Medical Product Service GmbH
Borngasse 20
35619 Braunfels, Germany

This Declaration of Conformity covers the **Duo-Flow Side x Side Catheters** as specified in the product list belonging to this declaration and is valid for all products concerned bearing the **CE** marking and manufactured at the following site:

Medical Components Inc. (dba. Medcomp®)
1499 Delp Drive
Harleysville, PA 19438 USA

I, the undersigned, hereby declare under my sole responsibility the equipment specified above meets the essential requirements and conforms to the following, as certified by B.S.I, Notified Body Identification Number 2797.

Date: 28 FEB 2019


Timothy Schweikert
President of
Medical Components Inc.
(dba. Medcomp®)
1499 Delp Drive
Harleysville, PA 19438 USA

Duo-Flow Side x Side Catheters (IIa)			
CATALOG CODES	PART NUMBER	DESCRIPTION	CE DATE
DL 11/15	1085	11F X 15CM DOUBLE LUMEN CRRT/ABP CATHETER SET	03/03/2001
DL 11/20	1086	11F X 20CM DOUBLE LUMEN CRRT/ABP CATHETER SET	03/03/2001
DL 9/15	1125	9FX15CM DOUBLE LUMEN CRRT/ABP CATHETER SET	11/26/1997
NDDLPC15	10011-815-112C	12F X 15CM PRE-CURVE DOUBLE LUMEN CATHETER	02/04/2014
NDDLPC20	10011-820-112C	12F X 20CM PRE-CURVE DOUBLE LUMEN CATHETER	02/04/2014
NDDLS20	10011-820-112	12F X 20CM DOUBLE LUMEN CATHETER	02/04/2014
NIDLC15K	10011-815-112C	12F (4.0MM) X 15CM (6") PRE-CURVED DOUBLE LUMEN CATHETER	09/26/2005
NIDLC20K	10011-820-112C	12F (4.0MM) X 20CM (8") PRE-CURVED DOUBLE LUMEN CATHETER	09/26/2005
NIDLPC15	10011-815-112C	12F (4.0MM) X 15CM (6") DOUBLE LUMEN PRE-CURVED CATHETER	08/16/2001
NIDLPC20	10011-820-112C	12F X 20CM DOUBLE LUMEN PRE-CURVED CATHETER	08/16/2001
NIDLS15	10011-815-112	12F (4.0MM) X 15CM (6") DOUBLE LUMEN CATHETER	08/16/2001
NIDLS15K	10011-815-112	12F (4.0MM) X 15CM (6") DOUBLE LUMEN CATHETER	09/26/2005
NIDLS20	10011-820-112	12F (4.0MM) X 20CM (8") DOUBLE LUMEN CATHETER	08/16/2001
NIDLS20K	10011-820-112	12F (4.0MM) X 20CM (8") DOUBLE LUMEN CATHETER	09/26/2005
NIDLS24	10011-824-112	12F (4.0MM) X 24CM (9.5") DOUBLE LUMEN CATHETER	08/16/2001
NIDLS24K	10011-824-112	12F (4.0MM) X 24CM (9.5") DOUBLE LUMEN CATHETER	09/26/2005
XTP114CT=	1084	11F X 12CM DOUBLE LUMEN CATHETER (CATHETER ONLY)	03/03/2001
XTP114IJC=	1176	11F X 12CM DOUBLE LUMEN CATHETER WITH CURVED EXTENSIONS (CATHETER ONLY)	03/03/2001
XTP114IJS=	1176	11F X 12CM DOUBLE LUMEN IJ CATHETER SET	03/03/2001

XTP114IJS= =	1176	11F X 12CM DOUBLE LUMEN IJ CATHETER SET	03/06/2002
XTP114MT=	1084	11F X 12CM DOUBLE LUMEN CATHETER SET	03/03/2001
XTP114IJS= JO	1176	11F X 12CM DOUBLE LUMEN IJ CATHETER SET	03/03/2001
XTP115IJS=	10540	11F X 13.5CM DOUBLE LUMEN IJ CATHETER SET	06/20/2011
XTP116CT=	1085	11F X 15CM DOUBLE LUMEN CATHETER (CATHETER ONLY)	03/03/2001
XTP116IJC=	1174	11F X 15CM DOUBLE LUMEN CATHETER WITH CURVED EXTENSIONS (CATHETER ONLY)	03/03/2001
XTP116IJS=	1174	11F X 15CM DOUBLE LUMEN IJ CATHETER SET	03/03/2001
XTP116IJS= =	1174	11F X 15CM DOUBLE LUMEN IJ CATHETER SET	03/06/2002
XTP116MT=	1085	11F X 15CM DOUBLE LUMEN CATHETER SET	03/03/2001
XTP116MT= .	1085	11F X 15CM DOUBLE LUMEN CATHETER SET	03/03/2001
XTP116MT= =	1085	11F X 15CM DOUBLE LUMEN CATHETER SET	03/06/2002
XTP116MT= ==	1085	11F X 15CM DOUBLE LUMEN CATHETER SET	09/17/2002
XTP116IJS= JO	1174	11F X 15CM DOUBLE LUMEN IJ CATHETER SET	03/03/2001
XTP118CT=	1086	11F X 20CM DOUBLE LUMEN CATHETER (CATHETER ONLY)	03/03/2001
XTP118IJC=	1175	11F X 20CM DOUBLE LUMEN CATHETER WITH CURVED EXTENSIONS (CATHETER ONLY)	03/03/2001
XTP118IJS=	1175	11F X 20CM DOUBLE LUMEN IJ CATHETER SET	03/03/2001
XTP118MT=	1086	11F X 20CM DOUBLE LUMEN CATHETER SET	03/03/2001
XTP118MT= .	1086	11F X 20CM DOUBLE LUMEN CATHETER SET	03/03/2001
XTP118MT= =	1086	11F X 20CM DOUBLE LUMEN CATHETER SET	03/06/2002
XTP118MT= ==	1086	11F X 20CM DOUBLE LUMEN CATHETER SET	09/17/2002
XTP119MT=	1246	11F X 24CM DOUBLE LUMEN CATHETER SET	09/30/2003

XTP125MTA	10011-813-100	12F X 13CM DOUBLE LUMEN CATHETER SET	11/01/2005
XTP125IJS=	10011-813-100C	12F X 13CM DOUBLE LUMEN IJ CATHETER SET	03/07/2005
XTP125IJS	10011-813-100C	12F X 13CM DOUBLE LUMEN IJ CATHETER SET	11/01/2005
XTP126IJS=	10011-815-100C	12F X 15CM DOUBLE LUMEN IJ CATHETER SET	03/07/2005
XTP126IJS	10011-815-100C	12F X 15CM DOUBLE LUMEN IJ CATHETER SET	11/01/2005
XTP126MT=	10011-815-100	12F X 15CM DOUBLE LUMEN CATHETER SET	03/07/2005
XTP126MT= ==	10011-815-100	12F X 15CM DOUBLE LUMEN CATHETER SET W/SYRINGE & SCALPEL	08/01/2007
XTP126MTA	10011-815-100	12F X 15CM DOUBLE LUMEN CATHETER SET	11/01/2005
XTP128IJS=	10011-820-100C	12F X 20CM DOUBLE LUMEN IJ CATHETER SET	04/03/2008
XTP128IJS	10011-820-100C	12F X 20CM DOUBLE LUMEN IJ CATHETER SET	11/01/2005
XTP128MT=	10011-820-100	12F X 20CM DOUBLE LUMEN CATHETER SET	03/07/2005
XTP128MT= ==	10011-820-100	12F X 20CM DOUBLE LUMEN CATHETER SET W/SYRINGE & SCALPEL	08/01/2007
XTP128MTA	10011-820-100	12F X 20CM DOUBLE LUMEN CATHETER SET	11/01/2005
XTP129IJS	10011-824-100C	12F X 24CM DOUBLE LUMEN IJ CATHETER SET	11/01/2005
XTP129MT=	10011-824-100	12F X 24CM DOUBLE LUMEN CATHETER SET	05/16/2008
XTP129MTA	10011-824-100	12F X 24CM DOUBLE LUMEN CATHETER SET	11/01/2005
XTP145IJS	10067-813-100C	14F X 13CM DOUBLE LUMEN W/CURVED EXTENSIONS SET	12/23/2005
XTP145MTA	10067-813-100	14F X 13CM DOUBLE LUMEN CATHETER SET	12/23/2005
XTP146IJS	10067-815-100C	14F X 15CM DOUBLE LUMEN W/CURVED EXTENSIONS SET	12/23/2005
XTP146MTA	10067-815-100	14F X 15CM DOUBLE LUMEN CATHETER SET	12/23/2005
XTP148IJS	10067-820-100C	14F X 20CM DOUBLE LUMEN W/CURVED EXTENSIONS SET	12/23/2005

XTP148MTA	10067-820-100	14F X 20CM DOUBLE LUMEN CATHETER SET	12/23/2005
XTP149IJS	10067-824-100C	14F X 24CM DOUBLE LUMEN W/CURVED EXTENSIONS SET	12/23/2005
XTP149MTA	10067-824-100	14F X 24CM DOUBLE LUMEN CATHETER SET	12/23/2005
XTP94IJS=	1177	9F X 12CM IJ CATH SET	03/03/2001
XTP94MT=	1124	9F X 12CM DOUBLE LUMEN CATHETER SET	03/03/2001
XTP96IJS=	1178	9F X 15CM INTERNAL JUGULAR CATHETER SET	12/06/2004
XTP96MT=	1125	9F X 15CM DOUBLE LUMEN CATHETER SET	03/03/2001
XTP98MT=	1126	9F X 20CM DOUBLE LUMEN CATHETER SET	03/03/2001
ARD1213C	10011-813-105C	12F X 13CM DOUBLE LUMEN JET CATH W/CURVED EXTENSIONS SET	03/03/2001
ARD1213S	10011-813-105	12F X 13CM DOUBLE LUMEN JET CATH SET	03/03/2001
ARD1215C	10011-815-105C	12F X 15CM DOUBLE LUMEN JET CATH W/CURVED EXTENSIONS SET	03/03/2001
ARD1215CG	10011-815-105C	12F X 15CM DOUBLE LUMEN JET CATH W/CURVED EXTENSIONS SET	03/01/2006
ARD1215S	10011-815-105	12F X 15CM DOUBLE LUMEN JET CATH SET	03/03/2001
ARD1215SG	10011-815-105	12F X 15CM DOUBLE LUMEN JET CATH SET	03/01/2006
ARD1220C	10011-820-105C	12F X 20CM DOUBLE LUMEN JET CATH W/CURVED EXTENSIONS SET	03/03/2001
ARD1220CG	10011-820-105C	12F X 20CM DOUBLE LUMEN JET CATH W/CURVED EXTENSIONS SET	03/01/2006
ARD1220S	10011-820-105	12F X 20CM DOUBLE LUMEN JET CATH SET	03/03/2001
ARD1220SG	10011-820-105	12F X 20CM DOUBLE LUMEN JET CATH SET	03/01/2006
ARD1224C	10011-824-105C	12F X 24CM DOUBLE LUMEN JET CATH W/CURVED EXTENSIONS SET	03/03/2001
ARD1224S	10011-824-105	12F X 24CM DOUBLE LUMEN JET CATH SET	03/03/2001

ARD1224SG	10011-824-105	12F X 24CM DOUBLE LUMEN JET CATH SET	03/01/2006
ARD1235C	10011-813-105C	12F X 13.5CM DOUBLE LUMEN JET CATH W/CURVED EXTENSIONS SET	03/01/2005
ARD1413C	10067-813-105C	14F X 13CM DOUBLE LUMEN JET CATH W/ CURVED EXTENSIONS SET	04/26/2005
ARD1413S	10067-813-105	14F X 13CM DOUBLE LUMEN JET CATH SET	04/26/2005
ARD1415C	10067-815-105C	14F X 15CM DOUBLE LUMEN JET CATH W/CURVED EXTENSIONS SET	04/26/2005
ARD1415S	10067-815-105	14F X 15CM DOUBLE LUMEN JET CATH SET	04/26/2005
ARD1420C	10067-820-105C	14F X 20CM DOUBLE LUMEN JET CATH W/CURVED EXTENSIONS SET	04/26/2005
ARD1420S	10067-820-105	14F X 20CM DOUBLE LUMEN JET CATH SET	04/26/2005
ARD1424C	10067-824-105C	14F X 24CM DOUBLE LUMEN JET CATH W/CURVED EXTENSIONS SET	04/26/2005
ARD1424S	10067-824-105	14F X 24CM DOUBLE LUMEN JET CATH SET	04/26/2005
ARD912S	1124	9F X 12CM DOUBLE LUMEN JET CATH SET	04/26/2005

Revision History			
Rev Level	Date Revised	Changes to the DOC	CR#
1	26OCT2018	CE Certificate Issued (Transferred from DNV GL Nemko Presafe AS)	23144
2	27FEB2019	Change "Side by Side" to "Side x Side" and updated notified body number	23910