Medical Components, Inc.
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DECLARATION OF CONFORMITY
Medical Devices
DoC-120

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 – Full Quality Assurance System" Certificate No. **CE 616020**, first issued on **15MAY2015** delivered by B.S.I, Notified Body Identification Number 2797, in accordance with Annex II, excl. Section 4 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 13485:2016 & EN ISO 13485:2016 Quality System Certification, MD 636611, 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 **Tri-Flow Catheter, Triple Lumen Jet Cath®, Triple Lumen Catheter & T-3® CT 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.
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: 23MAY2024

Martina Arno
Head of Regulatory Affairs
NA & EU of Medical Components Inc.
1499 Delp Drive
Harleysville, PA 19438
USA

Tri-Flow Catheter (IIa)			
CATALOG NUMBER	**PART NUMBER**	**DESCRIPTION**	**CE DATE**
XTP3126MT=	10106-815-000	12F X 15CM TRIPLE LUMEN CATHETER SET	05/16/2008
XTP3128MT=	10106-820-000	12F X 20CM TRIPLE LUMEN CATHETER SET	05/16/2008
XTP3129MT=	10106-824-000	12F X 24CM TRIPLE LUMEN CATHETER SET	05/16/2008
XTP3126IJS=	10106-815-000C	12F X 15CM TRIPLE LUMEN CATHETER W/CURVED EXTENSIONS SET	04/10/2008
XTP3128IJS=	10106-820-000C	12F X 20CM TRIPLE LUMEN CATHETER W/CURVED EXTENSIONS SET	04/10/2008
XTP3114MTE	1762	11.5F X 12CM TRI-FLOW CATHETER SET	03/03/2001
XTP3116MTE	1763	11.5F X 15CM TRI-FLOW CATHETER SET	03/03/2001
XTP3118MTE	1764	11.5F X 20CM TRI-FLOW CATHETER SET	03/03/2001
XTP3119MTE	1788	11.5F X 24CM TRI-FLOW CATHETER SET	07/29/2004
XTP3116MT-ID	1763	11.5F X 15CM TRI-FLOW TRIPLE LUMEN CATHETER SET W/MINI SCALPEL, SYRINGE AND NEEDLE	07/10/2008
XTP3118MT-ID	1764	11.5F X 20CM TRI-FLOW TRIPLE LUMEN CATHETER SET W/MINI SCALPEL, SYRINGE, & NEEDLE	09/25/2006
XTP3116IJSE	5443-815-000	11.5F X 15CM TRI-FLOW TRIPLE LUMEN CATHETER W/CURVED EXTENSIONS SET	02/27/2002
XTP3118IJSE	5443-820-000	11.5F x 20CM TRI-FLOW TRIPLE LUMEN CATHETER W/CURVED EXTENSIONS SET	08/13/2012

Triple Lumen Jet Cath®			
CATALOG NUMBER	**PART NUMBER**	**DESCRIPTION**	**CE DATE**
ART1213S	10106-812-005	12F X 12CM TRIPLE LUMEN JET-CATH SET	03/03/2001
ART1215S	10106-815-005	12F X 15CM TRIPLE LUMEN JET CATH SET	03/03/2001
ART1220S	10106-820-005	12F X 20CM TRIPLE LUMEN JET CATH SET	03/03/2001
ART1224S	10106-824-005	12F X 24CM TRIPLE LUMEN JET CATH SET	03/03/2001
ART1213C	10106-812-005C	12F X 12CM TRIPLE LUMEN JET CATH WITH CURVED EXTENSIONS SET	03/03/2001
ART1215C	10106-815-005C	12F X 15CM TRIPLE LUMEN JET CATH WITH CURVED EXTENSIONS SET	03/03/2001
ART1220C	10106-820-005C	12F X 20CM TRIPLE LUMEN JET CATH W/ CURVED EXTENSIONS SET	03/03/2001
ART1224C	10106-824-005C	12F X 24CM TRIPLE LUMEN JET CATH WITH CURVED EXTENSIONS SET	03/03/2001

Triple Lumen Catheter (IIa) (Nipro)			
CATALOG NUMBER	**PART NUMBER**	**DESCRIPTION**	**CE DATE**
NITLS15K	1763	11.5F X 15CM TRIPLE LUMEN CATHETER SET	06/09/2006
NITLS20K	1764	11.5F X 20CM TRIPLE LUMEN CATHETER SET	12/27/2005

Tri-Flow Catheter (IIa) (Nikkiso)			
CATALOG NUMBER	**PART NUMBER**	**DESCRIPTION**	**CE DATE**
XTP3114MTB	1762	11.5F X 12CM TRI-FLOW CRRT/ABP CATHETER SET	03/03/2001
XTP3116MTB	1763	11.5F X 15CM TRI-FLOW CRRT/ABP CATHETER SET	03/03/2001
XTP3118MTB	1764	11.5F X 20CM TRI-FLOW CRRT/ABP CATHETER SET	03/03/2001

T-3® CT Catheter (IIa)			
CATALOG NUMBER	**PART NUMBER**	**DESCRIPTION**	**CE DATE**
MC013501	10468-815-001	15.5F X 15CM T-3 TRIPLE LUMEN CT CATHETER BASIC SET	08/12/2011
MC013502	10468-820-001	15.5F X 20CM T-3 TRIPLE LUMEN CT CATHETER BASIC SET	08/12/2011
MC013503	10468-824-001	15.5F X 24CM T-3 TRIPLE LUMEN CT CATHETER BASIC SET	08/12/2011
MC013504	10468-828-001	15.5F X 28CM T-3 TRIPLE LUMEN CT CATHETER BASIC SET	08/12/2011
MC013505	10468-832-001	15.5F X 32CM T-3 TRIPLE LUMEN CT CATHETER BASIC SET	08/12/2011

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	Update notified body number	23910
3	05MAR2019	Obsolete Codes: MC011561, MC011562, MC011563, MC011564, MC011565, MC011571. MC011572, MC011573, MC011574, MC011575	23944
4	13MAR2019	Update to ISO13485:2016	23979
5	03JUL2019	Correct MD Cert (MD63661 to MD636611)	24320

6	21OCT2019	Reference BSI Reference # 9714917. Annex V to II Migration Add devices to the IIa table from CE 616021 Short Term Haemodialysis Catheters Typographical corrections: XTP3116MT-ID change “&” to “AND” ART1220C change “WITH” to “W/”	24802
7	06JUL2020	Update first issued date from 11AUG2016 to 15MAY2015	25491
8	05MAY2021	Updated to separate out catheter branding	26187
9	17MAR2023	Remove obsolete codes: XTP3116MTE. and XTP3118MTE. Update to DoC signee from Timothy Schweikert to Martina Arno per QA-R-2700.	27469
10	18JAN2024	Remove OBS codes (per CR 28759): XTP3114CTE, XTP3116CTE Remove OBS codes (per CR 28760): MC013544, MC013545 Remove (dba Medcomp®)	28759
11	08MAR2024	Remove obsolete code XTP3118MT=.	28935
12	24APR2024	Remove OBS codes (per CR 29016): MC013541, MC013542, MC013543, XTP3116MT=, XTP3118MT=	29016
13	16MAY2024	Remove OBS codes (per CR 28788): XTP3116MT=== and XTP3118MT===	28788