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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** delivered by B.S.I, Notified Body Identification Number 0086, 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 **Hemo-Cath ST 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 0086.

Date: 26 Oct 2018

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

Hemo-Cath ST (IIa)			
CATALOG CODE	PART NUMBER	DESCRIPTION	CE DATE
SLD11/15	3213G	11.5F X 15CM HEMO-CATH® SILICONE DOUBLE LUMEN CRRT/ABP CATHETER SET WITH STYLET	03/03/2001
SLD11/20	3275G	11.5F X 20CM HEMO-CATH® SILICONE DOUBLE LUMEN CRRT/ABP CATHETER SET WITH STYLET	03/03/2001
SLD11/24	3359G	11.5F X 24CM HEMO-CATH® SILICONE DOUBLE LUMEN CRRT/ABP CATHETER SET WITH STYLET	03/03/2001
SLD8/12	3310G	8F X 12CM HEMO-CATH® SILICONE DOUBLE LUMEN CRRT/ABP CATHETER SET	03/03/2001
SL12	3951G	11.5F X 12CM HEMO-CATH® SILICONE DOUBLE LUMEN CATHETER SET	03/03/2001
SL12P	3310G	8F X 12CM HEMO-CATH® SILICONE DOUBLE LUMEN CATHETER SET	03/03/2001
SL15	3213G	11.5F X 15CM HEMO-CATH® SILICONE DOUBLE LUMEN CATHETER SET W/STYLET	03/03/2001
SL15-ID	3213G	11.5F X 15CM SILICONE HEMO- CATH® SET WITH MINI SCALPEL, SYRINGE, AND NEEDLE	07/18/2008
SL15C	3213G	11.5F X 15CM HEMO-CATH® SILICONE DOUBLE LUMEN CATHETER W/STYLET	03/03/2001
SL15CIJ	3947	11.5F X 15CM HEMO-CATH® SILICONE DOUBLE LUMEN IJ CATHETER W/STYLET	03/03/2001
SL15E	3213G	11.5F X 15CM HEMO-CATH® SILICONE DOUBLE LUMEN CATHETER SET W/STYLET	03/03/2001
SL15E.	3213G	11.5F X 15CM HEMO-CATH® SILICONE DOUBLE LUMEN CATHETER SET W/STYLET	01/25/2002
SL15IJ	3947	11.5F X 15CM HEMO-CATH® SILICONE DOUBLE LUMEN IJ CATHETER WITH STYLET	08/29/2003



SL15IJS	3947	11.5F X 15CM HEMO-CATH® DOUBLE LUMEN IJ CATHETER SET	03/03/2001
SL20	3275G	11.5F X 20CM HEMO-CATH® SILICONE DOUBLE LUMEN CATHETER SET W/STYLET	03/03/2001
SL20-ID	3275G	11.5F X 20CM SILICONE HEMO-CATH® SET WITH MINI SCALPEL, SYRINGE, AND NEEDLE	06/05/2008
SL20C	3275G	11.5F X 20CM HEMO-CATH® SILICONE DOUBLE LUMEN CATHETER W/STYLET	03/03/2001
SL20E	3275G	11.5F X 20CM HEMO-CATH® SILICONE DOUBLE LUMEN CATHETER SET W/STYLET	03/03/2001
SL20E.	3275G	11.5F X 20CM HEMO-CATH® SILICONE DOUBLE LUMEN CATHETER SET W/STYLET	01/25/2002
SL24	3359G	11.5F X 24CM HEMO-CATH® SILICONE DOUBLE LUMEN CATHETER SET W/STYLET	03/03/2001
SL24C	3359G	11.5F X 24CM HEMO-CATH® SILICONE DOUBLE LUMEN CATHETER W/STYLET	03/03/2001
SL24E	3359G	11.5F X 24CM HEMO-CATH® SILICONE DOUBLE LUMEN CATHETER SET W/STYLET	03/03/2001
SL24E.	3359G	11.5F X 24CM HEMO-CATH® SILICONE DOUBLE LUMEN CATHETER SET W/STYLET	01/25/2002
SL27	30078G	11.5F X 27CM HEMO-CATH® SILICONE DOUBLE LUMEN CATHETER SET W/STYLET	08/21/2002
SSL1015M E.	3299	10F X 15CM SILICONE SINGLE LUMEN CATHETER SET W/STYLET & W/DILATOR	05/02/2001
SSL1215M	3297	12F X 15CM SILICONE SINGLE LUMEN CATHETER SET W/STYLET	03/03/2001
SSL1220M	3298	12F X 20CM SILICONE SINGLE LUMEN CATHETER SET W/STYLET	03/03/2001
SSL1220M E.	3298	12F X 20CM SILICONE SINGLE LUMEN CATHETER SET W/STYLET & W/DILATOR	05/02/2002
ECS1315	003290G	13.5F X 15CM SILICONE DOUBLE LUMEN CRRT/ABP CATHETER SET WITH STYLET	01/09/2003

ECS1320	003291G	13.5F X 20CM SILICONE DOUBLE LUMEN CRRT/ABP CATHETER SET WITH STYLET	01/09/2003
ECS1324	003292G	13.5F X 24CM SILICONE DOUBLE LUMEN CRRT/ABP CATHETER SET WITH STYLET	01/09/2003
ECS1328	3290-828-100	13.5F X 28CM SILICONE DOUBLE LUMEN CATHETER SET W/STYLET	03/08/2017
ECS1335	3290-835-100	13.5F X 35CM SILICONE DOUBLE LUMEN CATHETER SET W/STYLET	03/08/2017
SDL1311E	3290-828-100	13.5F X 28CM SILICONE DOUBLE LUMEN CATHETER SET W/STYLET	03/16/2006
SDL1314E	3290-835-100	13.5F X 35CM SILICONE DOUBLE LUMEN CATHETER SET W/STYLET	01/28/2008
SDL136E	003290G	13.5F X 15CM SILICONE DOUBLE LUMEN CATHETER SET W/STYLET	04/11/2007
SDL136E.	003290G	13.5F X 15CM SILICONE DOUBLE LUMEN CATHETER SET W/STYLET	04/11/2007
SDL138E	003291G	13.5F X 20CM SILICONE DOUBLE LUMEN CATHETER SET W/STYLET	04/11/2007
SDL138E.	003291G	13.5F X 20CM SILICONE DOUBLE LUMEN CATHETER SET W/STYLET	04/11/2007
SDL139E	003292G	13.5F X 24CM SILICONE DOUBLE LUMEN CATHETER SET W/STYLET	04/11/2007
SDL139E.	003292G	13.5F X 24CM SILICONE DOUBLE LUMEN CATHETER SET W/STYLET	04/11/2007

Revision History			
Rev Level	Date Revised	Changes to the DOC	CR#
1	26OCT2018	CE Certificate Issued (Transferred from DNV GL Nemko Presafe AS)	23144