



medCOMP

1499 Delp Drive

Harleysville, PA 19438

Tel: 215-256-4201

Fax: 215-256-1787

www.medcompnet.com

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

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 |