EU Declaration of Conformity

We,

Retractable Technologies, Inc.
511 Lobo Lane
Little Elm, Texas 75068-0009
United States of America

Declare and ensure with sole responsibility that the medical devices listed in page 2 of this declaration, meet the provisions of Council Directive 93/42/EEC (Medical Device Directive as amended on 2007-09-21) which apply to them. The obligations laid down in Annex II are fulfilled with a quality system approved for the design, manufacture and final inspection of the product(s) via certification issued by a Notified Body (bsi – No. 0086, EC Certificate 599210, effective July 26, 2013):

Number	Issue Date	Title
ANSI/AAMI HE74	2001	Human factors design process for medical devices
ASTM D4169	2009	Standard Practice for Performance Testing of Shipping Containers and Systems
BS EN ISO 11607-1	2009	Packaging for Terminally Sterilized Medical Devices Part 1
BS EN ISO 11607-2	2006	Packaging for terminally sterilized medical devices Part 2
ISO 6009	1992	Hypodermic Needles for Single Use - Colour Coding for Identification
BS EN 1041	2008	Information Supplied by the Manufacturer with Medical Devices
EN ISO 10993-1	2009	Biological evaluation of medical devices - Part 1: Evaluation and testing
BS EN ISO 11135-1	2014	Medical devices - Validation and routine control of ethylene oxide sterilization Part 1
BS EN ISO 11137-1	2006	Sterilization of health care products - Requirements for validation and routine control - Radiation sterilization Part 1
BS EN ISO 11137-2	2013	Sterilization of health care products. Radiation. Establishing the sterilization dose.
BS EN 556-1	2001	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE".
BS EN ISO 11737-1	2006	Sterilization of medical devices-Microbiological methods Part 1
BS EN ISO 11737-2	2009	Sterilization of medical devices-Microbiological methods Part 2
ISO 13485	2003	Medical devices — Quality management systems - Requirements for regulatory purposes
EN ISO 13485	2012	Medical devices — Quality management systems - Requirements for regulatory purposes
EN ISO 14971	2012	Medical devices — Application of risk management to medical devices
ISO 15223-1	2012	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied
ISO 7864	1993	Sterile hypodermic needles for single use
ISO 7886-1	1993	Sterile hypodermic syringes for single use – Part 1: Syringes for manual use
ISO 7886-4	2006	Sterile hypodermic syringes for single use – Part 4: Syringes with re-use prevention feature
ISO 8537	2007	Sterile single-use syringes, with or without needle, for insulin
ISO 23908	2011	Sharps injury protection-Requirements and test methods-Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling.
ISO 9626	1991	Stainless steel needle tubing for manufacture of medical devices
EN ISO 62366	2008	Medical devices: Application of usability engineering to medical devices

The representative for Retractable Technologies Inc. in the European Union is: MDSS (Medical Device Safety Service GmbH), Schiffgraben 41, D-30175 Hannover, Germany, for the above indicated products.

Regulatory Affairs Manager

January 7, 2016
Issue Date

August 1, 2018
Expiration Date

EU Declaration of Conformity
Continued Page 2

Product Description	*UMDNS #*	*Product Description*	*UMDNS #*
0.5cc/mL VanishPoint® Insulin syringe	18-071	1cc/mL VanishPoint® Dose Indicator syringe	18-070
1cc/mL VanishPoint syringe	18-070	2cc/mL VanishPoint® syringe	18-070
1cc/mL VanishPoint® Insulin syringe	18-071	3cc/mL VanishPoint® syringe	18-070
1cc/mL VanishPoint® Tuberculin syringe	18-072	5cc/mL VanishPoint® syringe	18-070
1cc/mL VanishPoint Allergy syringe	18-072	10cc/mL VanishPoint® syringe	18-070

EU Declaration of Conformity

We,

Retractable Technologies, Inc.
511 Lobo Lane
Little Elm, Texas 75068-0009
United States of America

Declare and ensure with sole responsibility that the following medical devices:

Product Description	*UMDNS #*	*Product Description*	*UMDNS #*
3cc/mL Patient Safe®Syringe	13929	20cc/mL Patient Safe®Syringe	13929
5cc/mL Patient Safe®Syringe	13929	30cc/mL Patient Safe®Syringe	13929
10cc/mL Patient Safe®Syringe	13929	60cc/mL Patient Safe®Syringe	13929
Patient Safe® Luer Cap	16825		

Meet the provisions of Council Directive 93/42/EEC (Medical Device Directive as amended on 2007-09-21) which apply to them. The obligations laid down in Annex II are fulfilled with a quality system approved for the design, manufacture and final inspection of the product(s) via certification issued by a Notified Body (bsi – No. 0086, EC Certificate 599210, effective July 26, 2013):

Number	Issue Date	Title
ANSI/AAMI HE74	2001	Human factors design process for medical devices
ASTM D4169	2009	Standard Practice for Performance Testing of Shipping Containers and Systems
BS EN ISO 11607-1	2009	Packaging for Terminally Sterilized Medical Devices Part 1
BS EN ISO 11607-2	2006	Packaging for terminally sterilized medical devices-Part 2
BS EN 1041	2008	Information Supplied by the Manufacturer with Medical Devices
EN ISO 10993-1	2009	Biological evaluation of medical devices - Part 1: Evaluation and testing
BS EN ISO 11135-1	2014	Medical devices - Validation and routine control of ethylene oxide sterilization Part 1
BS EN ISO 11737-1	2006	Sterilization of medical devices-Microbiological methods-Part 1
BS EN ISO 11737-2	2009	Sterilization of medical devices-Microbiological methods-Part 2
BS EN 556-1	2001	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices
ISO 13485	2003	Medical devices — Quality management systems - Requirements for regulatory purposes
EN ISO 13485	2012	Medical devices — Quality management systems - Requirements for regulatory purposes
EN ISO 14971	2012	Medical devices — Application of risk management to medical devices
ISO 15223-1	2012	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied
ISO 7886-1	1993	Sterile hypodermic syringes for single use – Part 1: Syringes for manual use
ISO 594-1	1986	Conical fittings with 6% (luer) taper for syringes, needles and certain other medical equipment-Part:1 General Requirements
EN ISO 62366	2008	Medical devices: Application of usability engineering to medical devices

The representative for Retractable Technologies Inc. in the European Union is: MDSS (Medical Device Safety Service GmbH), Sciffgraben 41, D-30175 Hannover, Germany, for the above indicated products.

Regulatory Affairs Manager

July 6, 2015
Issue Date

August 1, 2018
Expiration Date

EU Declaration of Conformity

We,

Retractable Technologies, Inc.
511 Lobo Lane
Little Elm, Texas 75068-0009
United States of America

Declare and ensure with sole responsibility that the following medical devices:

Product Description	*UMDNS #*
VanishPoint® I.V. Catheter	10-727
VanishPoint® I.V. Catheter-Ported	10-727

Meet the provisions of Council Directive 93/42/EEC (Medical Device Directive as amended on 2007-09-21) which apply to them. The obligations laid down in Annex II are fulfilled with a quality system approved for the design, manufacture and final inspection of the product(s) via certification issued by a Notified Body (bsi – No. 0086, EC Certificate 599210, effective July 26, 2013):

Number	Issue Date	Title
ASTM D4169	2009	Standard Practice for Performance Testing of Shipping Containers and Systems
BS EN ISO 11607-1	2009	Packaging for Terminally Sterilized Medical Devices Part 1
BS EN ISO 11607-2	2006	Packaging for terminally sterilized medical devices-Part 2
ISO 594-1	1986	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements
ISO 594-2	1998	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings
BS EN 1041	2008	Information Supplied by the Manufacturer with Medical Devices
ISO 9626	1991	Stainless steel needle tubing for manufacture of medical devices
ISO 10555-1	2013	Sterile, single-use intravascular catheters-Part 1: General requirements
ISO 10555-5	2013	Sterile, single use intravascular catheters-Part 5: Over-needle peripheral catheters
EN ISO 10993-1	2009	Biological evaluation of medical devices - Part 1: Evaluation and testing
BS EN ISO 11135-1	2014	Medical devices - Validation and routine control of ethylene oxide sterilization Part 1
BS EN ISO 11737-1	2006	Sterilization of medical devices-Microbiological methods-Part 1
BS EN ISO 11737-2	2009	Sterilization of medical devices-Microbiological methods-Part 2
BS EN 556-1	2001	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices
ISO 13485	2003	Medical devices — Quality management systems - Requirements for regulatory purposes
EN ISO 13485	2012	Medical devices — Quality management systems - Requirements for regulatory purposes
EN ISO 14971	2012	Medical devices — Application of risk management to medical devices
ISO 15223-1	2012	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied
EN ISO 62366	2008	Medical devices: Application of usability engineering to medical devices

The representative for Retractable Technologies Inc. in the European Union is: MDSS (Medical Device Safety Service GmbH), Sciffgraben 41, D-30175 Hannover, Germany, for the above indicated products.

Regulatory Affairs Manager

January 7, 2016
Issue Date

August 1, 2018
Expiration Date

Declaration of Conformity

We,

Retractable Technologies, Inc.
511 Lobo Lane
Little Elm, Texas 75068-0009
United States of America

Declare under our sole responsibility that the following products:

Product Description	*UMDNS #*
VanishPoint® Blood Collection Tube Holder	18-243
VanishPoint® Small Diameter Tube Adapter	18-243

to which this declaration relates is in conformity with the following standard(s) or other normative documents following the provisions of Annex VII the Medical Device Directive 93/42/EEC as amended on 2007-09-21:

Number	Issue Date	Title
ISO 14971	2012	Medical devices-Application of risk management to medical devices
ISO 15223-1	2012	Medical devices-Symbols to be used with medical device labels, labeling and information to be supplied-Part 1: General requirements
ISO 10993-1	2009	Biological evaluation of medical devices-Part 1: Evaluation and testing
ISO 13485	2003	Medical devices — Quality management systems - Requirements for regulatory purposes
EN ISO 13485	2012	Medical devices — Quality management systems - Requirements for regulatory purposes

The representative for Retractable Technologies Inc. in the European Union is: MDSS (Medical Device Safety Service GmbH), Sciffgraben 41, D-30175 Hannover Germany, for the above indicated products.

Regulatory Affairs Manager

July 15, 2014
Issue Date

August 1, 2018
Expiration Date

Declaration of Conformity

We,

Retractable Technologies, Inc.
511 Lobo Lane
Little Elm, Texas 75068-0009
United States of America

Declare and ensure with sole responsibility that the following medical devices:

Product Description	*UMDNS #*
Blood Collection Set	14183

Meet the provisions of Council Directive 93/42/EEC (Medical Device Directive as amended on 2007-09-21) which apply to them. The obligations laid down in Annex II are fulfilled with a quality system approved for the design, manufacture and final inspection of the product(s) via certification issued by a Notified Body (bsi – No. 0086, EC Certificate 599210, effective July 26, 2013):

Number	Issue Date	Title
ISO 594-1	1986	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment
ISO 594-2	1998	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment Part 2: Lock fittings
ISO 1135-4	2012	Transfusion equipment for medical use-Part 4: Transfusion sets for single use
ISO 6009	1992	Colour coding of hypodermic needles for single use
BS EN 1041	2008	Information Supplied by the Manufacturer with Medical Decices
ISO 7864:1993	1993	Sterile hypodermic needles for single use
ISO 8536-4	2010	Infusion equipment for medical use-Part 4: Infusion sets for single use, gravity feed
ISO 10555-1	2013	Sterile single-use intravascular catheters Part 1: General requirements
EN ISO 10993-1	2009	Biological Evaluation of Medical Devices-Part 1: Evaluation & Testing
BS EN ISO 11135-1	2014	Sterilization of health care products-Ethylene Oxide-Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
BS EN ISO 11737-1	2006	Sterilization of medical devices-Microbiological methods-Part 1
BS EN ISO 11737-2	2009	Sterilization of medical devices-Microbiological methods-Part 2
BS EN 556-1	2001	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices
BS EN ISO 11607-1	2009	Packaging for terminally sterilized medical devices-Part 1: Requirements for materials, sterile barrier systems and packaging systems
BS EN ISO 11607-2	2006	Packaging for terminally sterilized medical devices-Part 2: Validation requirements for forming, sealing and assembly processes
ISO 13485	2003	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 13485	2012	Medical devices – Quality management systems – Requirements for regulatory purposes
ISO 15223-1	2012	Medical Devices-Symbols to be used with Medical Device labels, Labeling, and Information to be supplied.
EN ISO 14971	2012	Medical devices-Application of risk management to medical devices
BS EN 62366	2008	Medical devices-Application of usability engineering to medical devices

The representative for Retractable Technologies Inc. in the European Union is: MDSS (Medical Device Safety Service GmbH), Sciffgraben 41, D-30175 Hannover, Germany, for the above indicated products.

Regulatory Affairs Manager

January 7, 2016
Issue Date

August 1, 2018
Expiration Date