Declaration of Conformity

Standard to Conformity is Declared:	Directive 98/79/EC, Annex III, Declaration of Conformity
Manufacturer's Name:	TriPath Imaging, Inc.
Manufacturer's Address:	780 Plantation Drive Burlington, NC 27215 USA
Product Number and Name:	491253 BD SurePath™ Collection Vial Kit 500 491324 BD SurePath™ Collection Vial Kit 25
Standards	93/112/EC, 94/62/EC, EN 13612, EN 13640, EN 13641, ISO 13485, EN ISO 13485, EN ISO 14971, EN 980, EN ISO 18113-1, EN ISO 18113-2, Regulation EC No. 1907/2006
Start of CE Marking:	September 13, 2013
Revision Date:	May 6, 2016
Authorized Representative:	Benex Limited
Authorized Representative Address:	Pottery Road, Dun Laoghaire Co. Dublin, Ireland Tel: +353.1.202.5222 / Fax: +353.1.202.5388

We TriPath Imaging, Inc. declare under our sole responsibility that the professional use product(s) listed above, manufactured under our Quality Assurance System, are in conformity with the provisions of European Directive 98/79/EC on *in vitro* diagnostic medical devices that apply to them and the transpositions into national laws. I, the undersigned, approve the placing of the CE marking on all product as defined in this declaration. All supporting documentation is retained under the premise of the manufacturer.

Raymond J. Boulé
(Signature)

May 6, 2016
(Date)

Raymond J. Boulé
(Printed Name)

Director, Regulatory Affairs
(Title)