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:	ProEx™ C Immunocytochemical Test Kit & Immunohistochemical Test, BD SureDetect™ Slide Preparation Buffer and SiHa Cell Control See attached list (one page)
Standards	93/112/EC, 94/62/EC, EN 13612, EN 13641, EN 13640, ISO 13485, EN ISO 13485, ISO 14971, ISO 15223-1, ISO 18113-1, ISO 18113-2, Regulation EC No. 1907/2006
Start of CE Marking:	July 27, 2006
Revision Date:	April 27, 2015
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 products as defined in this declaration. All supporting documentation is retained under the premise of the manufacturer.

(Signature) 5/7/15 (Date)

Mark Del Vecchio (Printed Name)

Sr. Director, Regulatory Affairs (Title)

DECLARATION OF CONFORMITY
PRODUCT LIST FOR
ProEx™ C Immunocytochemical Test Kit & Immunohistochemical Test, BD SureDetect™ Slide Preparation Buffer and SiHa Cell Control

Product Number	Product Name
490500	SurePath® with ProEx™ C Immunocytochemical Test – Counterstains
490501	SurePath® with ProEx™ C Immunocytochemical Test Kit
490502	BD ProEx™ C Immunohistochemical Test
490503	BD SureDetect™ SiHa Cell Control
490512	BD SureDetect™ Slide Preparation Buffer 10X