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:	BD Totalys™ Consumables See Attached List (one page)
Standards	93/112/EC, 94/62/EC, EC 1907/2006, EN 13612, EN 13640, EC 1272/2008 EN 13641, ISO 13485, EN ISO 13485, EN ISO 14971, EN 980, EN ISO 18113-1, EN ISO 18113-2
Start of CE Marking:	April 19, 2013
Revision Date:	April 29, 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.

(Signature) 29 April 2016 (Date)

Raymond J. Boulé (Printed Name) Director, Regulatory Affairs (Title)

DECLARATION OF CONFORMITY
PRODUCT LIST FOR
BD Totalys™ Consumables

Product Number	Product Name
491292	BD Totalys™ SlidePrep Install Kit
491304	BD Totalys™ SlidePrep Non-GYN Test Kit
491308	BD Totalys™ SlidePrep Consumables Kit
491310	BD Totalys™ MultiProcessor Consumables Kit
491388	BD Totalys™ SlidePrep Slide Library Kit
491389	BD Totalys™ MultiProcessor Installation Kit
491431	BD Totalys™ SlidePrep Slide Library Kit - Japan
491432	BD Totalys™ Non-GYN Test Kit - Japan