

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

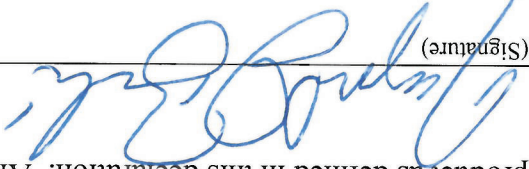
Authorized Representative Address: Pottery Road, Dun Laoghaire

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)



Raymond J. Boule

(Printed Name)

(Date)

29 April 2016

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