

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 Reagents and Consumables
See Attached List (One Page)

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

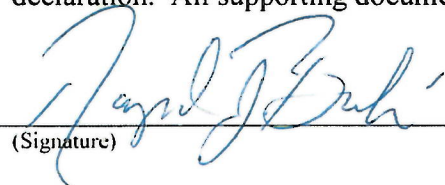
Start of CE Marking: April 19, 2013

Revision Date: May 31, 2017

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)

31 May 2017
(Date)

Raymond J. Boulé

(Printed Name)

Director, Regulatory Affairs

(Title)

DECLARATION OF CONFORMITY PRODUCT LIST FOR

BD Reagents and Consumables

Product Number	Product Name
490719	BD CytoRich™ Clear Preservative
491121	BD Alcohol Blend Rinse
491248	BD SurePath™ PreCoat Slides
491266	BD SurePath™ Manual Method Kit
491267	BD PrepStain™ Slide Library Kit
491288	BD PrepMate™ Installation Kit
491289	BD PrepStain™ Install Kit
491303	BD PrepStain™ Non-GYN Test Kit
491306	BD Density Reagent
491311	BD PrepStain™ Consumables Kit
491313	BD PrepMate™ Consumables Kit
491327	BD Hematoxylin Stain 0.5
491328	BD EA/OG Combo Stain
491329	BD Settling Chambers
491330	BD Settling Chambers
491331	BD Syringing Pipettes
491332	BD Density Reagent
491333	BD Non-GYN Stain Kit
491334	BD Cytology Stain Kit
491335	BD CytoRich™ Blue Preservative
491336	BD CytoRich™ Red Preservative
491337	BD SurePath™ Preservative Fluid
491338	BD Hematoxylin Stain 0.75
491443	BD CytoRich™ Clear Collection Vial
491433	BD PrepStain™ Non-GYN Test Kit - Japan
491434	BD PrepStain™ Slide Library Kit - Japan
491435	BD SurePath™ Manual Method Kit - Japan
491075	BD SurePath™ PreCoat Slides Japan