

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: PrepStain® Reagents and Disposables (See attached list)

Standards 93/112/EC, 94/62/EC, EN 13612, EN 13640, EN 13641, ISO 13485, EN ISO 13485, ISO 14971, EN ISO 15223-1, EN ISO 18113-1, EN ISO 18113-2, Regulation EC No. 1907/2006

Start of CE Marking: August 16, 2005

Revision Date: April 29, 2015

Authorized Representative: Benex Limited

Authorized Representative Address: Pottery Road, Dun Laoghaire
Co. Dublin, Ireland
Tel: +353.01.202.5222 / Fax: +353.01.202.5388

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)

(Date)

Mark Del Vecchio
(Printed Name)

Sr. Director, Regulatory Affairs
(Title)

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DECLARATION OF CONFORMITY
PRODUCT LIST FOR
PrepStain® Reagents and Disposables

Product Number	Product Name
490506	PrepStain® Alcohol Blend Rinse
490507	SurePath® Preservative Fluid
490508	CytoRich® Red Preservative
490509	CytoRich® Blue Preservative
490511	SurePath® PreCoat Slides
490521	PrepStain® Density Reagent
490522	SurePath® GYN Preservative Vial Kit
490523	PrepStain® GYN Cytology Test Kit
490527	SurePath® GYN Preservative Vial Kit
490528	PrepStain® Install Kit
490529	PrepStain® Manual Method 1 Kit
490531	PrepStain® Non-GYN Test Kit
490533	PrepStain® Non-GYN Blue Test Kit
490534	PrepStain® Non-GYN Red Test Kit
490536	PrepStain® Cytology Stain Kit
490537	PrepStain® Non-GYN Stain Kit
490540	SurePath™ 100 GYN Collection Kit
490541	GYN Slide Library, 480 Test
490544	PrepStain® 0.75 Hematoxylin Stain
490545	PrepStain® 0.5 Hematoxylin Stain
490628	PrepStain® EA/Orange-G Combo Stain
490720	BD CytoRich™ Non-GYN Test Kit
491247	BD SurePath™ GYN Cytology Test Kit

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