



Declaration of Conformity

Manufacturer:	Becton, Dickinson and Company 7 Loveton Circle Sparks, MD 21152 USA
Authorized Representative:	Benex Limited Pottery Road, Dun Laoghaire Co. Dublin, Ireland Tel: +353.1.202.5222 Fax: +353.1.202.5388
Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	491454 - BD PrepStain Consumables Kit (See Annex A for variants) -
We hereby declare that the above mentioned product(s) manufactured after 8/6/2018 complies with the European In Vitro Diagnostic Directive and its relevant transposition into national laws of the member states into which we place the devices. This declaration is issued under the sole responsibility of Becton, Dickinson and Company.	
Signed In Baltimore:	8/6/2018
Name and Authority:	Bradford M. Spring , VP, Regulatory Affairs
Signature:	

Technical File Number: BDDSTFCYTRGT

Annex A

BD Reagents and Consumables

BDDSTFCYTRGT

Version M

Primary Catalog Number and Product Name:

491454	BD PrepStain™ Consumables Kit
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Variants:

490719	BD CytoRich™ Clear Preservative
491075	BD SurePath™ PreCoat Slides Japan
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
491331	BD Syringing Pipettes
491332	BD Density Reagent
491335	BD CytoRich™ Blue Preservative
491336	BD CytoRich™ Red Preservative
491337	BD SurePath™ Preservative Fluid
491435	BD SurePath™ Manual Method Kit - Japan
491443	BD CytoRich™ Clear Collection Vial
491455	BD PrepMate™ Consumables Kit
491457	BD Alcohol Blend Rinse
491458	BD Cytology Stain Kit
491459	BD Non-GYN Stain Kit

Revision date: 2020/02/28

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