Declaration of Conformity

Manufacturer:	Becton, Dickinson and Company 7 Loveton Circle Sparks, MD 21152 USA Tel: +1.410.316.4000 Fax: +1.410.316.4499
Authorized Representative:	Benex Limited Pottery Road, Dun Laoghaire Co. Dublin, Ireland Tel: +353.1.202.5222 Fax: +353.1.202.5388
Conformity Assessment Procedure:	Directive 98/79/EC of the European Parliament and of the Council, Annex III of Directive 98/79/EC

Product:

REF	Product Name
442946	BD Onclarity HPV Assay Reagent Pack
441993	Control Set for the BD Onclarity HPV Assay
442840	BD Onclarity HPV Liquid Based Cytology Specimen (LBC) Diluent Tubes
442841	BD Viper PCR Extraction Reagent Trough with Piercing Tool
441992	BD FOX PCR Extraction Tubes
444869	BD HPV Self-Collection Diluent Tube

We hereby declare that the above mentioned product(s) manufactured after7/24/2019 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

Date:	December 10, 2020
Name and Authority:	Kay Taylor Vice President Regulatory Affairs, Life Sciences and IDS

Signature:

Kay A Taylor

Technical File Number: <BDDSTF442946>

RECORD REVISION HISTORY TABLE	
Revision	**Description of Changes**
A	**Initial SAP release. Transition to current format and added Cat# 444869 for self-collection tube/device**