BD 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:	228371 - BD Difco Shigella Antiserum Poly Group D (see Annex A for list of variants) -
	clare that the above mentioned product(s) manufactured after
2015/07/06 0	clare that the above mentioned product(s) manufactured after complies with the above listed Directive(s) and its relevant ito national laws of the member states into which we place the devices.
2015/07/06 0	complies with the above listed Directive(s) and its relevant to national laws of the member states into which we place the
2015/07/06 o transposition in Signed In	complies with the above listed Directive(s) and its relevant ito national laws of the member states into which we place the devices.

| Technical File Number: BALTER228371

<u>Annex A</u>

Difco Shigella Antiserum Poly Group D

BALTER228371 version B

Primary Catalog Number and Product Name:

228371	BD Difco™ Shigella Antiserum Poly Group D

Variants:

227761	BD Difco™ Shigella Antiserum Poly Group A1
227771	BD Difco™ Shigella Antiserum Poly Group C1
227781	BD Difco™ Shigella Antiserum Poly Group C2
228341	BD Difco™ Shigella Antiserum Poly Group A
228351	BD Difco™ Shigella Antiserum Poly Group B
228361	BD Difco™ Shigella Antiserum Poly Group C
228381	BD Difco™ Alkalescens-Dispar Antiserum Poly Contains Types 1-4