

DECLARATION OF CONFORMITY

We, Inverness Medical – BioStar Inc., 331 South 104th Street, Louisville, Colorado 80027, U.S.A., hereby declare that the products listed below,

Products:

Common name	Type	Order Code
Streptococcus A	STREP A OIA [®] MAX [®]	MAXINT
Streptococcus B	BioStar [®] OIA [®] STREP B	GBSINT
Respiratory Syncytial Virus	BioStar [®] OIA [®] RSV	RSVINT
Influenza Virus A/B	BioStar [®] OIA [®] FLU	FLU30INT
Influenza Virus A and B	BioStar [®] OIA [®] FLU A/B	FLUABINT
Clostridium difficile	BioStar [®] OIA [®] CdTOX A	CD30INT
	BioStar [®] OIA [®] CdTOX AB	CDABINT
Gonococcus	BioStar [®] OIA [®] GC	GC30INT
Accessory filter for GC	Urine Filtration Device (UFD)	UFDGCINT
Streptococcus A	BioStar [®] Acceava [®] Strep A	ACCGASINT
Mononucleosis	BioStar [®] Acceava [®] Mono	MONOINT
Trichomonas	BioStar [®] Acceava [®] Trichomonas	ACCTRCINT

to which this declaration relates, are in conformity with the essential requirements of Directive 98/79/EC, Article 9, paragraph 1, following Conformity Assessment requirements of Annex III.

Annex II, List B

Chlamydia	BioStar [®] OIA [®] CHLAMYDIA	CHLINT, CHLBMD
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To which this declaration relates, are in conformity with the essential requirements of Directive 98/79/EC, Article 9, paragraph 3, following Conformity Assessment requirements of Annex IV.

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