

MANUFACTURER: ADDRESS:	9500 Jeronimo Rd Irvine, CA 92618 UNITED STATES OF AMERICA	
EUROPEAN AUTHORIZED REPRESENTATIVE: ADDRESS:	Bio-Rad 3 boulevard Raymond Poincaré 92430 Marnes-la Coquette, France	
PRODUCT(S) NAME(S) Liquichek Sedimentation Rate Control	CATALOG NUMBER(S): 514, 514X, 515	
GENERIC DEVICE GROUP CODE: GMDN Nomenclature: 55972		
GENERIC DEVICE GROUP TERM: GMDN Nomenclature: Erythrocyte Sedimentation Rat	e (ESR) IVD, Control	
We hereby declare that the above mentioned product(s ⊠Directive 98/79/EC of the European Parliament and of		
CLASSIFICATION:		
☐ ANNEX II-A	☐ DEVICE FOR SELF TESTING	
☐ ANNEX II-B	☑ OTHER DEVICE	
CONFORMITY ROUTE ☑ ANNEX III ☐ ANNEX IV.3 Full Quality System ☐ ANNEX IV.4 Product EC Design Examination		
☐ ANNEX V EC Type Examination		
☐ ANNEX VII Production Quality System		
NEW PRODUCT(S) (Notification according to artic	cle 10 point 4) YES	⊠ NO
APPLICABLE HARMONIZED STANDARDS: Listed	in the Bio-Rad QSD Quality Manual Non Irvine, CA	mative References 22-Feb-19
Signature	Issued in	Date
Vindeep Kohli	Regulatory Affairs Manager	
Name	Function	

