



Declaration of Conformity



according to Directive 98/79/EC, on in vitro diagnostic medical devices

Maker (Name, Address)	Getein Biotech, Inc. No. 9 Bofu Road, Luhe District, Nanjing, 211505, China		
Authorized Representative (Name, Address)	Lotus Global Co., Ltd 15 Alexandra Road, London UK, NW8 0DP		
Medical device	Description :	FIA8000 Quantitative Immunoassay Analyzer Cardiac Troponin I Fast Test Kit One Step Test for NT-proBNP (Colloidal Gold) One Step Test for NT-proBNP/cTnI (Colloidal Gold) One Step Test for CK-MB/cTnI/Myo (Colloidal Gold) One Step Test for hs-CRP+CRP (Colloidal Gold) One Step Test for D-Dimer (Colloidal Gold) One Step Test for PCT (Colloidal Gold) One Step Test for β_2 -MG (Colloidal Gold) One Step Test for mAlb (Colloidal Gold) One Step Test for NGAL (Colloidal Gold) One Step Test for CysC (Colloidal Gold) One Step Test for HCG+ β (Colloidal Gold) One Step Test for CK-MB/cTnI (Colloidal Gold) One Step Test for CK-MB (Colloidal Gold) One Step Test for HbA1c (Colloidal Gold) One Step Test for TSH (Colloidal Gold) One Step Test for TSH/T3/T4 (Colloidal Gold)	
		Classification of products according to directive	: Others
		Batch/serial No. type, production term (if applicable)	:
Applicable coordination standards:	EN ISO 14971:2012 EN 980:2008 EN-ISO 18113-2:2011 EN ISO 18113-2:2011 EN-IEC 61326-1:2013 EN-IEC 61326-2-2:2013	EN ISO 23640:2015 EN 13612:2002 EN 1041:2008 EN ISO 18113-3:2011 EN-IEC 61010-1:2010	EN ISO 13485:2016 EN ISO15223-1:2012 EN ISO 18113-1:2011 IEC 61010-2-101:2015
Signatory representative declares herein the above mentioned device meets the basic requirements of the European Parliament and the Council's in vitro diagnostic medical devices directive: 98/79/EC Annex III. This declaration of conformity is based on European Parliament and the Council's 98/79/EC directive Annex III. The compiled technical file and quality system document according to 98/79/EC directive Annex III are testified and the quality system certificate has issued by TÜV Rheinland (Shanghai) Co., Ltd.			
General Manager: Enben Su			
Nanjing, 15th June, 2016 (place and date of issue)		 (name and signature or equivalent marking of authorized person)	