Declaration of Conformity

Manufacturer: Shenzhen Ultra-Diagnostics Biotec. Co., Ltd.
Address: Room 701, No.71-3, Xintian Avenue, Xintian Community, Fuhai Street, Baoan District, Shenzhen, P.R.China, 518103

European Representative: Wellkang Ltd
Address: Suite B, 29 Harley Street LONDON W1G 9QR,England,United Kingdom

Product: Thromboelastography Hemostasis Analyzer
Model Code: UD-T5000
EDMA CODE: 29011001
Classification (IVD): IVD Others
Conformity Assessment Route: Annex III

WE, SHEZHEN ULTRA-DIAGNOSTICS BIOTEC.CO., LTD.

Herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

In Vitro Diagnostic Medical Device Directive:DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices (IVD 98/79/EC).

STANDARD APPLIED

EN ISO13485:2016ENISO14971:2012 EN61010-2-101:2017
EN61010-1:2010EN61326-2-6:2013EN 61326-1:2013
EN 61010-2-081:2015EN1041:2008ENISO15223-1-2016

Start of CE Marking: Not Yet
Place, Date: SHENZHEN, 2019-12-1

Signature

Position : Management Representative