

EU Declaration of Conformity

Manufacturer: HANGZHOU ALLTEST BIOTECH CO., LTD.

Address: #550, Yinhai Street, Hangzhou Economic & Technological Development Area, Hangzhou
-310018, P.R. China

Single Registration Number: CN-MF-000010710

European Representative: MEDNET EC-REP GmbH

Address: Borkstrasse 10, 48163 Muenster, Germany

Single Registration Number: DE-AR-000000002

Product Name: Cholesterol Meter

Analyte: For the quantitative detection of the concentration of Total Cholesterol (CHOL),
High-density Lipoprotein Cholesterol (HDL) and Triglyceride (TRIG) in human whole blood, serum
and plasma.

REF: ACHR-100/ACHR-100ST

Model: Instrument

Classification according to Rule 5(b) of IVDR Annex VIII: Class A

Conformity Assessment Procedure: Annex II and III

EMDN Code: W0201069099

Basic UDI-DI: 6970277510016JYL

We, HANGZHOU ALLTEST BIOTECH CO., LTD, herewith declare that the EU declaration of
conformity is issued under the sole responsibility of above manufacturer. The above mentioned
product is in conformity with following Regulation and Standards:

Regulation Applied: REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE
COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC
and Commission Decision 2010/227/EU

Standard Applied: EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 15223-1:2021,
EN13612:2002/AC:2002, IEC 62366-1:2015, IEC 61010-2-101:2018, IEC 62304:2015, EN ISO
18113-1:2011, EN ISO 18113-3:2011, IEC 61326-1:2012, IEC 61326-2-6:2012, IEC
61010-1:2010/AMD1:2016

Place, Date of First Issue of DOC: in Hangzhou on 2023-07-26

Date of Issue of DOC on 2024-02-01

Signature: 

Name: Gao Fei

Position: General Manager