



DECLARATION OF CONFORMITY

Manufacturer: URIT Medical Electronic Co., Ltd.

Address: No. D-07 Information Industry District, High-Tech Zone, Guilin, Guangxi 541004, P.R. China

European Representative: Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Product:

- Urine Analyzer
- Model: UNAMAX LITE, UNAMAX ONE
- EDMA: 21.05.01.00
- GMDN: 57860

Applicable Standards:

EN ISO 14971:2012	ISO 13485-2016	ISO 780:2015
EN ISO 18113-1:2011	ISO 15223-1:2016	ISO 2859-1:1999/AMD1:2011
EN 13612:2002	EN 61326-1:2013	EN 61326-2-6:2013
EN 61010-1:2010+A1:2019	EN 61010-2-101:2017	EN, IEC 61000-3-2:2019
EN 61000-3-3:2013+A1:2019	EN ISO 18113-3-2011	

We, the manufacturer, herewith declares with sole responsibility that the product as specified above meets the applicable provisions of the standards mentioned above, and fulfils the obligations imposed by Annex III section 2 to 5 of Directive 98/79/EC. All supporting documentation is retained under the premise of authorized representative.

The above declaration of conformity is issued under the sole responsibility of the manufacturer.

Signed:

Place: Guilin, China

Date: 2021.03.12

Name of authorized signatory: Shi Ping

Position held in the company: CEO

Seal/Stamp:

URIT Medical Electronic Co., Ltd.