DECLARATION OF CONFORMITY

According to the In Vitro Diagnostic Medical Directive 98/79/EC

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:

- Automated Hematology Analyzer
- Model: URIT-3000Plus/URIT-3020/URIT-2900Plus/BH-70P/BH-40P

Category: Other.

EDMA:23.02.02.00

Digitally signed by Varman Irina
Date: 2024.12.10 14:58:51 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

GMDN:35476

Conformity assessment route: Annex III, except section 6.

Applicable Standards:

ISO 13485:2016	EN ISO 14971:2019	EN ISO 15223-1:2021
EN ISO 18113-3:2011	EN ISO 18113-1:2011	EN 13612:2002
EN 61010-1:2010	EN 61326-2-6:2013	EN 61000-3-2:2014
EN 61000-3-3:2013	EN 61010-2-101:2017	

We, the manufacturer, herewith declares with sole responsibility that the product as specified above meets the applicable provisions of the following the Directive and 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: 2022.04.13

Name of authorized signatory: Shi Ping
Position held in the company: CEO
Seal/Stamp:
URIT Medical Electronic Co.,Ltd.