

**URIT 优利特**

**CE Technical Document**

**Declaration of Conformity**

**(Detergent)**

**(Model:URIT D46)**

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Prepared by:

*Xiong Ling*

Technical Engineer

Verified by:

*Huangqinbin*


Technical Manager


Approved by:

*Su Qinghua*

PRRC

**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: Eifflstrasse 80, 20537 Hamburg, Germany
Product Name:	Detergent
Model:	URIT D46
GMDN Code:	63377
EMDN Code:	W0103010105
SRN:	CN-MF-000011840
Basic UDI-DI:	69357404IBHS000001AZ
Device Photograph:	
Intended Use:	With the function of cleaning, it has an important effect to clinical diagnosis.
Risk Class:	Class A
Classification Rule:	Rule 5 (a) of Annex VIII of the Regulation (EU) 2017/746
Conformity Assessment Route	Article 48 section 10 of the Regulation (EU) 2017/746
We herewith declare that the above-mentioned product(s) meet the Regulation (EU) 2017/746 of THE EUROPEAN PARLIAMENT AND OF THE COUNCIL. All supporting documentation is retained at the premises of the manufacturer. We, the manufacturer, are exclusively responsible for the DoC.	
Applied Standards:	EN ISO 13485:2016 EN ISO 14971:2019 EN ISO 15223-1:2021 EN ISO 18113-2: 2022 EN ISO 18113-1:2022 EN ISO 23640: 2015 EN 13612: 2002

Notified Body:	NA		
Identification Number:	NA		
(EC) Certificate(s):	NA	Valid until	NA
Start of CE-marking:			
Place, Date of Issue:	Guilin, Guangxi 2023-12-8		
Signature:	 <i>Shiping</i> Name: Shi Ping Function: CEO		