URIT 优利特

CE Technical Document

Declaration of Conformity

(Lyse)

（Model:URIT 5L 11）

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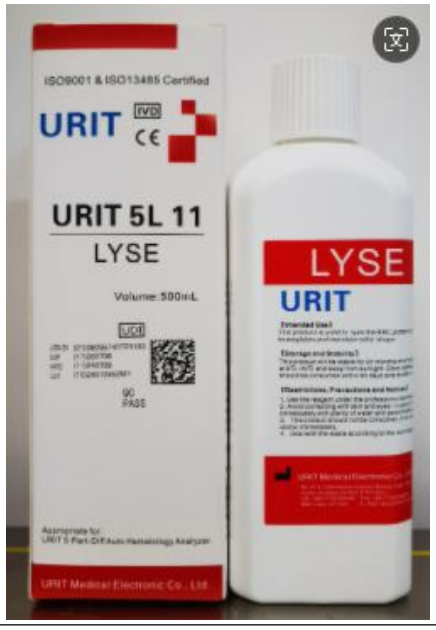
Declaration of Conformity

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 Name:	Lyse
Model:	URIT 5L 11
GMDN Code:	61165
EMDN Code:	W0103010105
SRN:	CN-MF-000011840
Basic UDI-DI:	69357404IBHS000003B5
Device Photograph:	
Intended Use:	This product is used to lyse the RBC promptly, release the hemoglobin and maintain cells' shape.
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: 2024 EN ISO 18113-1:2024 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 2024-9-30	
Signature:		Name: Function:	