URIT优利特

CE Technical Document

Declaration of Conformity

(Diluent)

(Model:URIT D31)

Document No: IVDR-URIT D31-CE09

Version/Revision No: 1.0

Department Distributed: Department II

Prepared by:		Verified by:	Approved by:	
Xiong	Ling	Huang 9 in bin	Su Oingue	
Technical Engineer		Technical Manager	PRRC	

Declaration of Conformity

Deciaration of Conformity				
URIT Medical Electronic Co., Ltd.				
Manufacturer:	Address: No. D-07 Information Industry District, High-Tech Zone, Guilin,			
	Guangxi 541004, P. R. China			
European	Shanghai International Holding Corp. GmbH (Europe)			
Representative:	Address: Eiffestrasse 80, 20537 Hamburg, Germany			
Product Name:	Diluent			
Model:	URIT D31			
GMDN Code:	35781			
EMDN Code:	W0103010105			
SRN:	CN-MF-000011840			
Basic UDI-DI:	69357404IBHS000005B9			
Device Photograph:	DEST.			
Intended Use:	Diluent is appropriate to series of URIT automated hematology analyzers. With the function of measuring the blood cell content, 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	Article 48 section 10 of the Regulation (EU) 2017/746			
Assessment Route				
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 premis	ses of the manufacturer. We, the manufacturer, are exclusively responsible for			
the DoC.				
	EN ISO 13485:2016/AC:2018			
	EN ISO 14971:2019			
Applied Standards:	EN ISO 15223-1:2021			
	EN ISO 18113-2: 2011			
	EN ISO 18113-1:2011			

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		EN ISO 23640: 2015			
		EN 13612: 2002			
Notified Body:		NA			
Identification					
Number:		NA			
(EC)					
Certificate(s):	NA	Valid until	NA		
Start of		2022-3-20			
CE-marking:		2022-3-20			
Place, Date of					
Issue:		Guilin, 2022-3-20			
Signature:		Shiping Name: Function: CEO			
03000000000					

URIT优利特

CE Technical Document

Declaration of Conformity

(Probe Cleaner)

(Model:URIT D43)

Document No: IVDR-URIT D43-CE09

Version/Revision No: 1.0

Department Distributed: Department II

Prepared by:		Verified by:	Approved by:
Xiong	Ling	Huang Qin bin	Zhou Yong Yang
Technical Engineer		Technical Manager	PRRC

1. Declaration of Conformity

URIT Medical Electronic Co., Ltd.			
Address: No. D-07 Information Industry			
District, High-Tech Zone, Guilin, Guangxi			
541004, P. R. China			
Shanghai International Holding Corp. GmbH			
(Europe)			
Address: Eiffestrasse 80, 20537 Hamburg,			
Germany			
Probe Cleaner			
URIT D43			
53377			
W0103010105			
CN-MF-000011840			
59357404IBHS000002B3			
UNIT PROVISIONS			
Probe Cleaner used with blood cell analysis, to			
clean the instrument's probe or pipe. And it			
also can be used for daily maintenance.			
Class A			
Rule 5 (a) of Annex VIII of the Regulation (EU) 2017/746			
Article 48 section 10 of the Regulation (EU) 2017/746			
duct(s) meet the Regulation (EU) 2017/746 of			
COUNCIL. All supporting documentation is			
retained at the premises of the manufacturer. We, the manufacturer, are exclusively responsible for			
the DoC.			
EN ISO 13485:2016/AC:2018			
211 100 10 100 120 101110 120 10			
EN ISO 14971:2019			
EN ISO 14971:2019			
EN ISO 14971:2019 EN ISO 15223-1:2021			

Document No:IVDR-URIT D43-CE-09(Version 1.0)

		EN 13612: 2002		
Notified Body:		NA	NA	
Identification Number:		NA	NA	
(EC) Certificate(s):	NA	Valid until NA		
Start of CE-marking:		2022-3-20	2022-3-20	
Place, Date of Issue:		Guilin, 2022-3-20	Guilin, 2022-3-20	
Signature:		Name:	ing	

URIT优利特

CE Technical Document

Declaration of Conformity

(Lytic Reagent)

(Model:URIT L21)

Document No: IVDR-URIT L21-CE09

Version/Revision No: 1.0

Department Distributed: Department II

Prepared by:	Verified by:	Approved by:
Xiong Lin	9 Huang Qin bin	Zhou Yong Yang
Technical Engineer	Technical Manager	PRRC

Declaration of Conformity

	URIT Medical Electronic Co., Ltd.		
N. C.	Address: No. D-07 Information Industry		
Manufacturer:	District, High-Tech Zone, Guilin, Guangxi		
	541004, P. R. China		
	Shanghai International Holding Corp. GmbH		
	(Europe)		
European Representative:	Address: Eiffestrasse 80, 20537 Hamburg,		
	Germany		
Product Name:	Lytic Reagent		
Model:	URIT L21		
GMDN Code:	61165		
EMDN Code:	W0103010105		
SRN:	CN-MF-000011840		
Basic UDI-DI:	69357404IBHS000003B5		
Device Photograph:	SAME A SO DATE CANAL SAME A SOLUTION OF THE PARTY OF THE		
	Lytic Reagent is appropriate to series of URIT		
Intended Use:	automated hematology analyzers. With the		
intended ose.	function of measuring the blood cell content, it		
	has an important effect to clinical diagnosis.		
Risk Class:	Class A		
Classification Rule:	Rule 5 (a) of Annex VIII of the Regulation		
Classification Ruic.	(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.				
		EN ISO 13485:2016/A	C:2018	
		EN ISO 14971:2019		
		EN ISO 15223-1:2021		
Applied Standards:		EN ISO 18113-2: 2011		
		EN ISO 18113-1:2011		
		EN ISO 23640: 2015		
		EN 13612: 2002		
Notified Body:		NA		
Identification Number:		NA		
(EC) Certificate(s):	NA	Valid until NA		
Start of CE-marking:		2022-3-20		
Place, Date of Issue:	and the	Guilin, 2022-3-20		
Signature:	THE WANTED	Name:		
		Function	: CEO	