URIT 优利特

CE Technical Document

Declaration of Conformity

(Diluent)

(Model:URIT D31)

Document No: IVDR-URIT D31-CE09

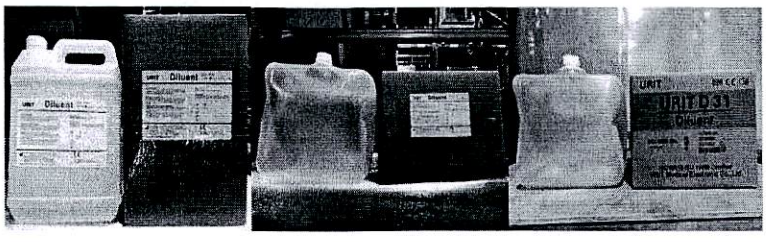
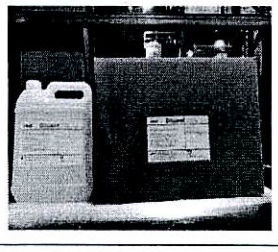
Version/Revision No: 1.0

Department Distributed: Department II

Prepared by:	Verified by:	Approved by:
Xiong Ling	Huangqinbin	Su Qingwa
Technical Engineer	Technical Manager	PRRC

Digitally signed by Varman Irina
Date: 2024.01.17 10:22:38 EET
Reason: MoldSign Signature
Location: Moldova

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:	Diluent
Model:	URIT D31
GMDN Code:	35781
EMDN Code:	W0103010105
SRN:	CN-MF-000011840
Basic UDI-DI:	69357404IBHS000005B9
Device Photograph:	 
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 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/AC:2018 EN ISO 14971:2019 EN ISO 15223-1:2021 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:	Guilin, 2022-3-20		
Signature:	Name: Shiping Function: CEO		

URIT 优利特

CE Technical Document

Declaration of Conformity

(Probe Cleaner)

(Model:URIT D43)

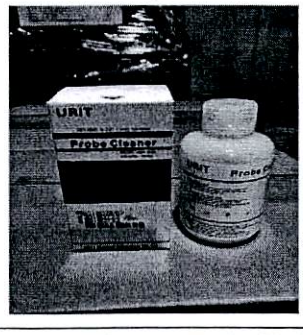
Document No: IVDR-URIT D43-CE09

Version/Revision No: 1.0

Department Distributed: Department II

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

1. 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:	Probe Cleaner
Model:	URIT D43
GMDN Code:	63377
EMDN Code:	W0103010105
SRN:	CN-MF-000011840
Basic UDI-DI:	69357404IBHS000002B3
Device Photograph:	
Intended Use:	Probe Cleaner used with blood cell analysis, to clean the instrument's probe or pipe. And it also can be used for daily maintenance.
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/AC:2018 EN ISO 14971:2019 EN ISO 15223-1:2021 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:		Guilin, 2022-3-20	
Signature:		Name: Shiping Function: CEO	

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 Ling	Huangqinbin	Zhou Yong Yang
Technical Engineer	Technical Manager	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: 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:	
Intended Use:	Lytic Reagent 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 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/AC:2018 EN ISO 14971:2019 EN ISO 15223-1:2021 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:		Guilin, 2022-3-20	
Signature:		Name: Shiping Function: CEO	