

# Agrupación Salud

Fabricado por / manufactured by Merufa



## DECLARATION CONFORMITY LETTER THƯ CÔNG BỐ SẢN PHẨM PHÙ HỢP

DISTRIBUTION (Nhà phân phối): MERUFA JOINTSTOCK COMPANY LTD.

PRODUCT NAME (Tên Sản Phẩm): MERUFA TOP LATEX EXAMINATION GLOVES

DATE (Ngày): 18 May 2020

AS A DISTRIBUTITION, WE DECLARE THAT:  
Là nhà phân phối, chúng tôi công bố rằng:

THE PRODUCT CONCERNED HAS BEEN DESIGNED AND MANUFACTURED UNDER A QUALITY MANAGEMENT SYSTEM IN COMPLIANCE WITH DIRECTIVE 93/42/EEC 2019

Sản phẩm được thiết kế và sản xuất theo hệ thống quản lý chất lượng tuân thủ hướng dẫn quy định 93/42/EEC:2019

FOLLOWING THE PROCEDURE RELATING TO THE CE DECLARATION OF CONFORMITY SET OUT IN COMPLIANCE WITH DIRECTIVE 93/42/EEC: 2019

Theo thủ tục liên quan đến công bố sản phẩm phù hợp với CE hướng dẫn quy định 93/42/EEC:2019

AND OUR PRODUCT MEET TECHNICAL REQUIREMENT OF FOLLOWING DIRECTIVES AND STANDARDS: EN455-2:2011 METHOD EN420:2003 + A1:2009, ASTM D6319-19, ISO9001:2015, ISO 13485:2016 WITH CERTIFICATE NUMBER ISO 086/8.19.14 and ISO 024/1.19.TA1

Và sản phẩm chúng tôi đạt tiêu chuẩn kỹ thuật theo quy định và tiêu chuẩn EN455-2:2011 phương pháp EN420:2003 + A1:2009, tiêu chuẩn của Mỹ ASTM D6319-19, ISO9001:2015, ISO 13485:2016 với số chứng nhận ISO 086/8.19.14 và ISO 024/1.19.TA1

THIS DECLARATION OF CONFORMITY IS VALID IN CONNECTION THE RELEASE DOCUMENT FOR THE RESPECTIVE BATCH OF THE PRODUCED DEVICES

Công bố sản phẩm phù hợp này có giá trị liên quan đến các giấy tờ phát hành cho các lô hàng thiết bị tương ứng.

## CERTIFICATE

This is to certify that the Quality Management System of

### MERUFA JOINT STOCK COMPANY

Head Office: No. 38 Truong Quoc Dung Street, Ward 8, Phu Nhuan District, Ho Chi Minh City, Vietnam  
Factory: C64/II, Road No. 8, Vinh Loc Industrial Park, Binh Chanh District, Ho Chi Minh City, Vietnam

has been assessed and found to conform with the requirements of

### TCVN ISO 13485:2017/ ISO 13485:2016

**Certificate Scope:** Manufacture and Supply of Medical Devices: Condoms, Medical devices disposable made from rubber(Surgical gloves, Medical examination gloves, Medical Gloves, Penrose drain, Medical catheters, Tourniquet buckles,...), Male external Catheter, Medical Gel (Ultrasound transmission and Lubricating Gel)

**Certificate Number:** ISO 024/1.19.TA1

**The validity of this Certificate:** from 04 November 2019 to 03 November 2022

**Original Certification:** 04 November 2016

**CÔNG TY CỔ PHẦN MERUFA  
MERUFA JOINTSTOCK CO., LTD.**

38 TRUONG QUOC DUNG STREET, WARD 8, PHU NHUAN DISTRICT, HOCHIMINH CITY, VIETNAM

**DECLARATION CONFORMITY LETTER  
THƯ CÔNG BỐ SẢN PHẨM PHÙ HỢP**

DISTRIBUTION (Nhà phân phối): MERUFA JOINTSTOCK COMPANY LTD.

PRODUCT NAME (Tên Sản Phẩm): MERUFA TOP LATEX EXAMINATION GLOVES

DATE (Ngày): 18 May 2020

AS A DISTRIBUTION, WE DECLARE THAT:

Là nhà phân phối, chúng tôi công bố rằng:

THE PRODUCT CONCERNED HAS BEEN DESIGNED AND MANUFACTURED UNDER A QUALITY MANAGEMENT SYSTEM IN COMPLIANCE WITH DIRECTIVE 93/42/EEC 2019

Sản phẩm được thiết kế và sản xuất theo hệ thống quản lý chất lượng tuân thủ hướng dẫn quy định 93/42/EEC:2019

FOLLOWING THE PROCEDURE RELATING TO THE CE DECLARATION OF CONFORMITY SET OUT IN COMPLIANCE WITH DIRECTIVE 93/42/EEC: 2019

Theo thủ tục liên quan đến công bố sản phẩm phù hợp với CE hướng dẫn quy định 93/42/EEC:2019

AND OUR PRODUCT MEET TECHNICAL REQUIREMENT OF FOLLOWING DIRECTIVES AND STANDARDS: EN455-2:201 METHOD EN420:2003 + A1:2009, ASTM D6319-19, ISO9001:2015, ISO 13485:2016 WITH CERTIFICATE NUMBER ISO 086/8.19.14 and ISO 024/1.19.TA1

Và sản phẩm chúng tôi đạt tiêu chuẩn kỹ thuật theo quy định và tiêu chuẩn EN455-2:201 phương pháp EN420:2003 + A1:2009, tiêu chuẩn của Mỹ ASTM D6319-19, ISO9001:2015, ISO 13485:2016 với số chứng nhận ISO 086/8.19.14 và ISO 024/1.19.TA1

THIS DECLARATION OF CONFORMITY IS VALID IN CONNECTION THE RELEASE DOCUMENT FOR THE RESPECTIVE BATCH OF THE PRODUCED DEVICES

Công bố sản phẩm phù hợp này có giá trị liên quan đến các giấy tờ phát hành cho các lô hàng thiết bị tương ứng.

DISTRIBUTOR REPRESENTATIVE:

Đại diện nhà phân phối:



**TỔNG GIÁM ĐỐC**  
**Cn. Lưu Tiên Cáo**

European Representative: Unique New Buil S.L.U.

Name: Javier Hernández Aguirre

Address: Calle órese 19, 7D, Marid, Spain.



# CERTIFICATE

*This is to certify that the Quality Management System of*

## MERUFA JOINT STOCK COMPANY

Head Office: No. 38 Truong Quoc Dung Street, Ward 8, Phu Nhuan District, Ho Chi Minh City, Vietnam

Factory: C64/II, Road No. 8, Vinh Loc Industrial Park, Binh Chanh District, Ho Chi Minh City, Vietnam

*has been assessed and found to conform with the requirements of*

## TCVN ISO 9001:2015/ISO 9001:2015

**Certification Scope:**

Manufacture and Supply of Medical devices: Condoms, Medical devices disposable made from rubber (Surgical gloves, Medical examination gloves, Medical gloves, Penrose drain, Medical catheters, Tourniquet buckles,...), Rubber stopper, Male external catheter, Medical gel (Ultrasound transmission and Lubricating gel)

**Certificate Number:**

HT 086/8.19.14

**The validity of this Certificate:**

from 04 November 2019 to 03 November 2022

**Original Certification:**

10 June 2000



The Director General of STAMEQ

The Chairman of the Certification Board

The Director of QUACERT

MSc. Tran Van Vinh

Dr. Pham Hong



MSc. Pham Le Cuong







# CERTIFICATE

*This is to certify that the Quality Management System of*

## **MERUFA JOINT STOCK COMPANY**

**Head Office: No. 38 Truong Quoc Dung Street, Ward 8, Phu Nhuan District, Ho Chi Minh City, Vietnam**

**Factory: C64/II, Road No. 8, Vinh Loc Industrial Park, Binh Chanh District, Ho Chi Minh City, Vietnam**

*has been assessed and found to conform with the requirements of*

## **TCVN ISO 13485:2017/ ISO 13485:2016**

**Certification Scope:** Manufacture and Supply of Medical Devices: Condoms, Medical devices disposable made from rubber (Surgical gloves, Medical examination gloves, Medical Gloves, Penrose drain, Medical catheters, Tourniquet buckles,...), Male external Catheter, Medical Gel (Ultrasound transmission and Lubricating Gel)

**Certificate Number:** ISO 024/1.19.TA1

**The validity of this Certificate:** from 04 November 2019 to 03 November 2022

**Original Certification:** 04 November 2016

The Director General of STAMEQ

Handwritten signature of MSc. Tran Van Vinh in blue ink.

**MSc. Tran Van Vinh**

The Chairman of the Certification Board

Handwritten signature of Dr. Pham Hong in blue ink.

**Dr. Pham Hong**

The Director of QUACERT



**MSc. Pham Le Cuong**





# Certificate of Compliance

Application for  
Medical Device Directive (MDD) 93/42/EEC.

This is to certify that the product(s):

**Surgical Gloves; Latex Examination Gloves; Nitrile Examination Gloves; Contraceptive Condoms**

Manufactured by

**MERUFA JOINT STOCK COMPANY**

Head Office: No.38 Truong Quoc Dung Street, Ward 8,  
Phu Nhuan District, Ho Chi Minh City, Vietnam

Factory: C64/II, Road No.8, Vinh Loc Industrial Park, Vinh Loc Commune,  
Binh Chanh District, Ho Chi Minh City, Vietnam

Complies with the requirement of the  
"Test Standard: EN 455:2015; EN ISO 4074:2014"

has been assessed & found in accordance with the requirements of  
**MDD 93/42/EEC as amended by 2007/47/EC Class I (Non-Sterile).**

QCC is non-notified certification body, issue this  
'compliance certificate' after audit of manufacturer product(s) & technical file(s).

This certificate applies to the tested sample only not for whole production.

It's manufacturer sole responsibility to meet all the necessary conformity  
assessment activities according to **MDD 93/42/EEC** and related standards  
before placing them on the market & CE mark on the product(s).

Certificate No. : **CE/017180/0720**

Original Certificate Date : 03 - July - 2020

Issue Date : 03 - July - 2020

Expiry Date : 02 - July - 2021



To check this certificate status visit:  
"<http://uasl.uk.com/certifiedorganization.html>"

Authorised Signature

**For Quality Control Certification**

UK Office: 1929, Chynoweth House,  
Trevissome Park, Truro-TR48UN, Cornwall, UK



Quality Control Certification accredited by UASL, UK  
This certificate doesn't provide the certified organisation with immunity from its legal obligations.  
This certificate remains the property of QC Certification to whom it must be returned on request.