



Health Technology Certification

## QUALITY MANAGEMENT SYSTEM CERTIFICATE

This is to certify that the quality management system of

**Ultra for medical  
products (Ultramed) Co  
(U.M.I.C) S.A.E.**

**Part No. (304:310) & part no.(312) - Industrial Area,  
Arab El Awamer - Abnoub - Assiut - Egypt**

has been assessed by HTCert and found to comply with

**EN ISO 9001:2015**

Scope of certificate:

**Manufacturing of  
General Non-Active, Non-Implantable, Sterile Medical Devices  
as detaily presented overleaf**

|                    |                      |
|--------------------|----------------------|
| Certificate No:    | <b>1421C01200501</b> |
| Original Approval: | <b>21/05/2020</b>    |
| References:        | <b>W001 1421 01</b>  |
| Issue Date:        | <b>21/05/2020</b>    |
| Valid until:       | <b>20/05/2023</b>    |

For and on behalf of HTCert

**GEORGE PAPPOUS**  
Managing Director

**FILIPPOS KOTTIS**  
Certification Director





Health Technology Certification

# Attachment to Certificate

No: 1421C01200501

Issued: 21/05/2020

## Products included in the certification scope

- Sterile Intravenous Infusion Sets with and without needle.
- Sterile Blood Transfusion Sets.
- Sterile Umbilical Cord clamps.
- Sterile Urine Bags.
- Sterile I.V. Cannulas.
- Sterile Surgical Gloves.
- Sterile Guedel Airway.
- Sterile Mucus Extractors.
- Sterile Burette Sets.
- Sterile Nelaton Catheters.
- Sterile Suction Catheters.
- Sterile Suction Units.
- Sterile Ryle's Tubes.
- Sterile Infant Feeding Tubes.
- Sterile 3 ways Stop Cocks.
- Sterile Nasal Oxygen Cannulas.
- Sterile Silicon Foley Catheters.
- Sterile Latex Foley Catheters.
- Sterile Fistula Needles.
- Sterile Oxygen Masks.
- Sterile Flow Regulators.
- Sterile IV Tubing.
- Sterile Endotracheal Tubes with and without cuff.
- Sterile Extension Tubes with and without stop cock

For and on behalf of HTCert

**GEORGE PAPPOUS**  
Managing Director

A blue ink signature of George Pappous, written in a cursive style.

**FILIPPOS KOTTIS**  
Certification Director

A blue ink signature of Filippou Kottis, written in a cursive style.





Health Technology Certification

## QUALITY MANAGEMENT SYSTEM CERTIFICATE

This is to certify that the quality management system of

**Ultra for medical  
products (Ultramed) Co  
(U.M.I.C) S.A.E.**

**Part No. (304:310) & part no.(312) - Industrial Area,  
Arab El Awamer - Abnoub - Assiut - Egypt**

has been assessed by HTCert and found to comply with

**EN ISO 13485:2016**

Scope of certificate:

**Manufacturing of  
General Non-Active, Non-Implantable, Sterile Medical Devices  
as detaily presented overleaf**

|                    |                      |
|--------------------|----------------------|
| Certificate No:    | <b>1421C02200501</b> |
| Original Approval: | <b>21/05/2020</b>    |
| References:        | <b>W001 1421 01</b>  |
| Issue Date:        | <b>21/05/2020</b>    |
| Valid until:       | <b>20/05/2023</b>    |

For and on behalf of HTCert

**GEORGE PAPPOUS**  
Managing Director

**FILIPPOS KOTTIS**  
Certification Director





Health Technology Certification

# Attachment to Certificate

No: 1421C02200501

Issued: 21/05/2020

## Products included in the certification scope

- Sterile Intravenous Infusion Sets with and without needle.
- Sterile Blood Transfusion Sets.
- Sterile Umbilical Cord clamps.
- Sterile Urine Bags.
- Sterile I.V. Cannulas.
- Sterile Surgical Gloves.
- Sterile Guedel Airway.
- Sterile Mucus Extractors.
- Sterile Burette Sets.
- Sterile Nelaton Catheters.
- Sterile Suction Catheters.
- Sterile Suction Units.
- Sterile Ryle's Tubes.
- Sterile Infant Feeding Tubes.
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- Sterile Silicon Foley Catheters.
- Sterile Latex Foley Catheters.
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- Sterile Oxygen Masks.
- Sterile Flow Regulators.
- Sterile IV Tubing.
- Sterile Endotracheal Tubes with and without cuff.
- Sterile Extension Tubes with and without stop cock.

For and on behalf of HTCert

GEORGE PAPPOUS  
Managing Director

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FILIPPOS KOTTIS  
Certification Director

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**ULTRA FOR MEDICAL PRODUCTS CO.**

## Declaration of Conformity

**Manufacturer's Name** : Ultra for medical products (Ultramed) Co (U.M.I.C) S.A.E.

**Manufacturer's Address** : Part No. (304:310) & part no. (312) -  
Industrial Area, Arab El Awamer - Abnoub -  
Assiut - Egypt

**Internet** : [www.ultramedumic.com](http://www.ultramedumic.com)

### **Authorized Representative (AR)**

**Name** : Obelis<sup>SA</sup>

**Address** : Bd. Général Wahis 53  
1030 Brussels - Belgium

**Phone** : +32 (0)2 732 59 54

**Fax** : +32 (0)2 732 60 03

**E-mail** : [mail@obelis.net](mailto:mail@obelis.net)

**Internet** : [www.obelis.com](http://www.obelis.com)

We hereby declare that the distributed CE marked products, specified in the attached product list, conform to the type covered by the provisions of the Council Directive 93/42/EEC, June 1993 concerning medical devices amended by Directive 2007/47/EC, September 2007 under the supervision of the Notified Body the Notified Body "HT CERT" (CE 2803).

Based on

**Certificate No.** : 1421C05201201

**Issue Date** : 14/12/2020

**Expiry Date** : 26/05/2024

- G.F.I. Health Technology Certification Ltd

**Address** : Jakovides Tower 81 - 83 Grivas Digenis

Av., CY 1090, Nicosia Cyprus

**Phone** : +357 (22) 503000

**Fax** : +357 (22) 503001

**Internet** : [www.htcert.com](http://www.htcert.com)

In addition, we ensure and declare that the distributed CE marked products, as mentioned, meet the provisions of the EC-Directive that apply to them.

This declaration is based on MDD 93/42/EEC (Annex-VII) & is subject to the procedure set out in Annex-V of directive 93/42/EEC, June 1993 amended by Directive 2007/47/EC, September 2007.

We also declare that the finished product shall conform to the specifications and functional requirements for 5 years from the date of sterilization.

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**Declaration of Conformity**

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**ULTRA FOR MEDICAL PRODUCTS CO.**

Storage Conditions: Not more than 5 cartoons on each other, Nice Ventilated place, Out of Sun light and a suitable temperature (18 – 32 °C).

**Attached List:**

| #   | Product Name                                         | Classification |
|-----|------------------------------------------------------|----------------|
| 1.  | Intravenous Infusion Set (I.V. Infusion Set)         | Ila            |
| 2.  | Intravenous Cannula (I.V. Cannula)                   | Ila            |
| 3.  | Blood Administration Set (Blood Transfusion Set)     | Ila            |
| 4.  | Extension Tube with/ without Three Way Stop Cock     | I              |
| 5.  | Three Way Stop Cock                                  | I              |
| 6.  | Arterial Venous Fistula Needle (A.V. Fistula Needle) | Ila            |
| 7.  | Infant Feeding Tube                                  | Ila            |
| 8.  | Ryle's Tube                                          | Ila            |
| 9.  | Suction Catheter                                     | Ila            |
| 10. | Nelaton Catheter                                     | Ila            |
| 11. | Mucus Extractor                                      | Ila            |
| 12. | Umbilical Cord Clamp                                 | I              |
| 13. | Close Wound Suction Unit (Hemosuc)                   | Ila            |
| 14. | Urine Collection Bag (Adult - Paediatric)            | I              |
| 15. | Guedel Airway                                        | Ila            |
| 16. | Burette Set                                          | Ila            |
| 17. | Endotracheal Tube (Cuffed - Uncuffed)                | Ila            |
| 18. | Latex Foley Catheter                                 | Ila            |
| 19. | Silicon Foley Catheter                               | Ila            |
| 20. | Nasal Oxygen Cannula (Adult - Paediatric - Neonatal) | Ila            |
| 21. | Surgical Gloves Ultra Easy                           | Ila            |
| 22. | Surgical Gloves Ultra Touch                          | Ila            |
| 23. | Oxygen Face Mask (Adult - Paediatric)                | Ila            |
| 24. | Flow Regulator                                       | Ila            |
| 25. | Suction Tube ( Yankaur & Handle)                     | Ila            |

**General Manager**

**Dated on: - 20/12/2020**



**Assiut Factory:** Part No. 304, 305, 306, 307, 308, 309, 310, 312, Arab El Awamer- industrial zone, Abnoub, Assiut, Egypt.. **Tel:** 002-088-4964333 (500), 002-088-4964666 (600), 002-088-4964777 (700), 002-088-4964888 (800), 002-088-4964999 (900)  
**& Fax:** 002-088-4964222 & **Mob:** 002-01001558853, 002-01068832355  
**Cairo Head Office:** 64, Nakhla El Motayy Triumph Square Heliopolis **Tel:** 022/4171621-4143794 & **Fax:** 022/4171613 & **Mob:** 01223988200  
**Assiut Office:** 23, July Str. **Tel:** 088/2364111 – 2364222 & **Fax:** 088/2334964 & **Mob. :** 01223988202  
**Alexandria Office:** 212Abd El salaam Airef Str, Luran **Tel:** 03/5856202– 5856458 & **Fax:** 03/58289888 & **Mob:** 01223948666  
**E-mail:** [ultra@elaggargroup.com](mailto:ultra@elaggargroup.com), [shady@elaggargroup.com](mailto:shady@elaggargroup.com) **Website:** [www.ultramedumic.com](http://www.ultramedumic.com)

**Declaration of Conformity**

ISSUE/REV: - 1/0

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Health Technology Certification

# EC-CERTIFICATE

## PRODUCTION QUALITY ASSURANCE

This is to certify that the  
quality management system of

### **Ultra for medical products (Ultramed) Co (U.M.I.C) S.A.E.**

Part No. (304:310) & part no. (312) – Industrial  
Area, Arab El Awamer – Abnoub - Assiut - Egypt  
for manufacturing and final testing of

### **Sterile Disposable Medical Devices** *Further details are given overleaf*

**Certificate No:** 1421C05201201  
**Issue Date:** 14/12/2020  
**Original Approval:** 14/12/2020  
**Valid until:** 26/05/2024  
**References:** W001 1421 01

HTCert is a Notified Body according  
to Council Directive 93/42/EEC concerning  
medical devices with identification  
number 2803

fulfills the requirements of Annex V of Council Directive 93/42/EEC.

The use of CE Marking followed by the HTCert Notified Body identification number 2803 for the devices listed on the certificate is hereby authorised. The certificate remains valid subject to satisfactory surveillance audits, periodic or unexpected. Any significant changes in design or manufacture may render this certificate invalid. For class I sterile devices the certificate covers only the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with a measuring function the certificate covers only the aspects of manufacture concerned with the conformity of the products with metrological requirements.

For and on behalf of HTCert

**GEORGE PAPPOUS**  
Managing Director

**FILIPPOS KOTTIS**  
Certification Director



Health Technology Certification

## Attachment to Certificate

No: 1421C05201201

Issued: 14/12/2020

Devices / device categories included in the certificate

### Class I sterile devices:

- 3 ways Stop Cocks.
- Extension Tubes with and without stop cock.
- Umbilical Cord clamps.
- Urine Collection Bags.

### Class IIa devices:

- Intravenous Infusion Sets with and without needle.
- Blood Transfusion Sets.
- I.V. Cannulas.
- Burette Sets.
- Endotracheal Tubes with and without cuff.
- Flow Regulators.
- Guedel Airway.
- Mucus Extractors.
- Nelaton Catheters.
- Suction Catheters.
- Suction Units.
- Ryle's Tubes.
- Infant Feeding Tubes.
- Surgical Gloves.
- Nasal Oxygen Cannulas.
- Silicon Foley Catheters.
- Latex Foley Catheters.
- Fistula Needles.
- Oxygen Masks.

For and on behalf of HTCert

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Managing Director

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