



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:	1421C01200501
Original Approval:	21/05/2020
References:	W001 1421 01
Issue Date:	21/05/2020
Valid until:	20/05/2023

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

FILIPPOS KOTTIS
Certification Director





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:	1421C02200501
Original Approval:	21/05/2020
References:	W001 1421 01
Issue Date:	21/05/2020
Valid until:	20/05/2023

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.
- 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 Filippos Kottis, written in a cursive style.





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

Authorized Representative (AR)

Name : Obelis^{SA}

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

Internet : 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

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.

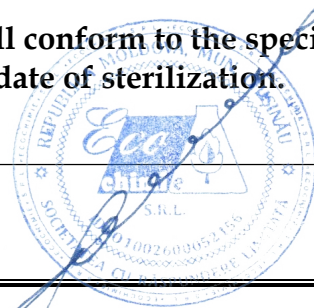
This declaration is based on MDD 93/42/EEC (Annex-VII) & is subject to the procedure set out in Annex-V of directive 93/42/EEC, June 1993 amended by Directive 2007/47/EC, September 2007.

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

Declaration of Conformity

ISSUE/REV: - 1/0

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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 Motaiy 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:** 03/5828988**& Mob:** 01223948666

E-mail: ultra@elaggargroup.com, shady@elaggargroup.com

Website: 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



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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

GEORGE PAPPOUS
Managing Director

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