HTCert

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:	WO01 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

IAS ACCREDITED
Management Systems Certification Body

JACOVIDES TOWER, 81-83 GRIVAS DIGHENIS AV. CY-1090, NICOSIA, CYPRUS, T: +357 220 60 771, F: +357 220 60 772
info@htcert.com, www.htcert.com

HTCert

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

IAS ACCREDITED
Management Systems Certification Body

JACOVIDES TOWER, 81-83 GRIVAS DIGHENIS AV. CY-1090, NICOSIA, CYPRUS, T: +357 220 60 771, F: +357 220 60 772
info@htcert.com, www.htcert.com

HTCert

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:	WO01 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

IAS ACCREDITED
Management Systems Certification Body

JACOVIDES TOWER, 81-83 GRIVAS DIGHENIS AV. CY-1090, NICOSIA, CYPRUS, T: +357 220 60 771, F: +357 220 60 772
info@htcert.com, www.htcert.com

HTCert

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

FILIPPOS KOTTIS
Certification Director

IAS ACCREDITED
Management Systems Certification Body

JACOVIDES TOWER, 81-83 GRIVAS DIGHENIS AV. CY-1090, NICOSIA, CYPRUS, T: +357 220 60 771, F: +357 220 60 772
info@htcert.com, www.htcert.com

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.

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 ^{O}C).

Attached List:

#	Product Name	Classification
1.	Intravenous Infusion Set (I.V. Infusion Set)	IIa
2.	Intravenous Cannula (I.V. Cannula)	IIa
3.	Blood Administration Set (Blood Transfusion Set)	IIa
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)	IIa
7.	Infant Feeding Tube	IIa
8.	Ryle's Tube	IIa
9.	Suction Catheter	IIa
10.	Nelaton Catheter	IIa
11.	Mucus Extractor	IIa
12.	Umbilical Cord Clamp	I
13.	Close Wound Suction Unit (Hemosuc)	IIa
14.	Urine Collection Bag (Adult – Paediatric)	I
15.	Guedel Airway	IIa
16.	Burette Set	IIa
17.	Endotracheal Tube (Cuffed – Uncuffed)	IIa
18.	Latex Foley Catheter	IIa
19.	Silicon Foley Catheter	IIa
20.	Nasal Oxygen Cannula (Adult – Paediatric – Neonatal)	IIa
21.	Surgical Gloves Ultra Easy	IIa
22.	Surgical Gloves Ultra Touch	IIa
23.	Oxygen Face Mask (Adult – Paediatric)	IIa
24.	Flow Regulator	IIa
25.	Suction Tube (Yankaur & Handle)	IIa

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
Assuit 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

HTCert

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:	**WO01 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

JACOVIDES TOWER, 81-83 GRIVAS DIGHENIS AV. CY-1090, NICOSIA, CYPRUS, T: +357 220 60 771, F: +357 220 60 772
info@htcert.com www.htcert.com

HTCert
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

FILIPPOS KOTTIS
Certification Director

JACOVIDES TOWER, 81-83 GRIVAS DIGHENIS AV. CY-1090, NICOSIA, CYPRUS, T: +357 220 60 771, F: +357 220 60 772
info@htcert.com www.htcert.com