



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

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.

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