

Declaration of Conformity

Latex Foley Catheter

- Manufacturer's Name** : Ultra For medical products Co (U.M.I.C).
- Manufacturer's Address** : Part No. (304:310) & part no. (312) – Industrial Area, Arab El Awamer – Abnoub - Assiut – Egypt.
- Intended use** : The Foley Catheter is a tubular device intended for being introduced into the urinary bladder through the urethra in order to provide drainage, drug delivery and/or flushing of the bladder.
- Internet** : www.ultramedumic.com
- Classification Rule** : Class IIa - Rule no. 5 (Annex-IX) in accordance of the Council Directive MDD 93/42/EEC of 14 June 1993 amended by Directive 2007/47/EC, September 2007.
- 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 "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

ULTRA FOR MEDICAL PRODUCTS CO.

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

This declaration is based on MDD 93/42/EEC Annex II (- Sect. 4) of directive 93/42/EEC, June 1993 amended by Directive 2007/47/EC, September 2007.

Attached List:

Code	Item
3006-6/2	Latex Foley Balloon Catheter Size 6 FG / 2-Way
3006-8/2	Latex Foley Balloon Catheter Size 8 FG / 2-Way
3006-10/2	Latex Foley Balloon Catheter Size 10 FG / 2-Way
3006-12/2	Latex Foley Balloon Catheter Size 12 FG / 2-Way
3006-14/2	Latex Foley Balloon Catheter Size 14 FG / 2-Way
3006-16/2	Latex Foley Balloon Catheter Size 16 FG / 2-Way
3006-18/2	Latex Foley Balloon Catheter Size 18 FG / 2-Way
3006-20/2	Latex Foley Balloon Catheter Size 20 FG / 2-Way
3006-22/2	Latex Foley Balloon Catheter Size 22 FG / 2-Way
3006-24/2	Latex Foley Balloon Catheter Size 24 FG / 2-Way
3006-16/3	Latex Foley Balloon Catheter Size 16 FG / 3-Way
3006-18/3	Latex Foley Balloon Catheter Size 18 FG / 3-Way
3006-20/3	Latex Foley Balloon Catheter Size 20 FG / 3-Way
3006-22/3	Latex Foley Balloon Catheter Size 22 FG / 3-Way
3006-24/3	Latex Foley Balloon Catheter Size 24 FG / 3-Way


General Manager

Dated on: - 20/12/2020



Assiut Factory: Part No. (304:310) & part no. (312) – Industrial Area, Arab El Awamer – 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

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