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

Date: 12 February 2024

Confirmation Letter
Reference: EG_038562_2024_01

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, HTCert, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2803 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR from the following manufacturer:

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
SRN: EG-MF-000038562

Application ID: EG_038562_24_01_04
Application Date: 03/02/2024

The devices covered by the formal application mentioned above and for which the NB will be responsible for appropriate surveillance under the applicable Directive are identified below.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)

- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Filippos Kottis
Certification Director

Devices covered by this letter

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Intravenous Infusion Sets with and without needle.	Class IIa device	n/a	1421C05201201 NB 2803
Blood Transfusion Sets.	Class IIa device	n/a	1421C05201201 NB 2803
I.V. Cannulas.	Class IIa device	n/a	1421C05201201 NB 2803
Burette Sets.	Class IIa device	n/a	1421C05201201 NB 2803
Endotracheal Tubes with and without cuff.	Class IIa device	n/a	1421C05201201 NB 2803
Flow Regulators.	Class IIa device	n/a	1421C05201201 NB 2803
Guedel Airway.	Class IIa device	n/a	1421C05201201 NB 2803
Mucus Extractors.	Class IIa device	n/a	1421C05201201 NB 2803
Nelaton Catheters.	Class IIa device	n/a	1421C05201201 NB 2803
Suction Catheters.	Class IIa device	n/a	1421C05201201 NB 2803
Suction Units.	Class IIa device	n/a	1421C05201201 NB 2803
Ryle's Tubes.	Class IIa device	n/a	1421C05201201 NB 2803
Infant Feeding Tubes.	Class IIa device	n/a	1421C05201201 NB 2803

Surgical Gloves.	Class IIa device	n/a	1421C05201201 NB 2803
Nasal Oxygen Cannulas.	Class IIa device	n/a	1421C05201201 NB 2803
Silicon Foley Catheters.	Class IIa device	n/a	1421C05201201 NB 2803
Latex Foley Catheters.	Class IIa device	n/a	1421C05201201 NB 2803
Fistula Needles.	Class IIa device	n/a	1421C05201201 NB 2803
Oxygen Masks.	Class IIa device	n/a	1421C05201201 NB 2803
3 ways Stop Cocks.	Class Is device	n/a	1421C05201201 NB 2803
Extension Tubes with and without stop cock.	Class Is device	n/a	1421C05201201 NB 2803
Umbilical Cord clamps.	Class Is device	n/a	1421C05201201 NB 2803
Urine Collection Bags	Class Is device	n/a	1421C05201201 NB 2803

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/02/12	EG_038562_2024_01	Initial issue