

# ACCREDITED DECLARATION OF CONFORMITY

## Medical Device Directive, 93/42/EEC+2007/47/EC



**Manufacturer Name:** MEDTİM GRUP MEDİKAL MALZ. DAN. BİL. YAZ. İNŞ. SAN. VE TİC. LTD.ŞTİ.  
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**Product Name** : **Wound Washing and Drainage System with Accessories**

**Brand**



**Purpose of Usage** : A sterile device assembly designed to pulsatilely spray a sterile fluid (usually saline) into general soft tissue or orthopedic surgical fields to irrigate, wash and remove debris (e.g., site cleaning, removal of bone cement residues, for soft tissue wound or bone debridement). It typically consists of a handpiece with integrated battery-powered pump and irrigation/suction controls, a disposable battery box, tubing and removable tips (applicators) of different shapes and sizes certain surgical operations. It is a disposable device.

**GMDN No** : 47890-Battery powered disposable surgical / orthopedic lavage system  
**Sterilization Status** : Steril/ EO

**Harmonized Standards** : EN 60601-1, EN ISO 15223-1, EN ISO 13485, EN ISO 14971, EN 20417, EN ISO 10993-1, EN ISO 10993-5, EN ISO 10993-10, EN ISO 10993-12, EN ISO 11737-1, EN ISO 11737-2, EN ISO 11607-1, EN ISO 11607-2, EN ISO 11135-1, EN 556-1, EN 62366-1

**Class / Rule** : IIa/ Rule 11

**Conformity Examination** : ANNEX II (Section 4 exempt)

**Notified Body :** UDEM International Certification  
**Notified Body No :** 2292  
**Certificate No :** M.2018.106.9150  
**First Release Date :** 05.01.2018  
**Validity Date :** 26.09.2024

**Declaration :** The product whose name, description, product model number and similar information is given above has CE mark on it. The product meets the requirements of the 93/42/EEC+2007/47/EC medical devices directive (this directive allows the free circulation and sale of the above-mentioned product in all European Union countries). All supporting documentation is maintained at Medtim Grup Medikal Malz. Dan. Bil. Yaz. İnş. İml. San ve Tic. Ltd. Şti.'s facilities. This Conformity identifies that medical devices corresponding to all product model numbers mentioned above are manufactured by Medtim Grup Medikal Malz. Dan. Bil. Yaz. İnş. İml. San ve Tic. Ltd. Şti and included in the certified Quality System Documentation. The Declaration of Conformity is valid 26.09.2024

**Our Product Reference Numbers :** LL-XXX : With Light, LLI-XXX : Without Light  
**Date :** 03.01.2023

**Signature :** General Manager  
Onur Emre GÜL

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