



93/42/EEC-2007/47/EC Medical

Devices Directive

DECLARATION OF CONFORMITY

Company Name : Sterilmed Medical Elektrik, Elektronik, Otomasyon, İnşaat, Gıda, Sanayi ve Dış Ticaret Ltd. Şti.
Address : Başkent Organize Sanayi Bölgesi 18.Cadde No:43 Maliköy Sincan Ankara -Türkiye
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Web / E-mail : www.sterilmed.com.tr / info@sterilmed.com.tr

We, as manufacturer of this product, herewith declare under our sole responsibility that the below mentioned products mentioned above:

Product : Washer Disinfector
GMDN Code : 35424
Model Code :

Product	Brand	Model	GMDN Code	UNSPSC Code	Class
Washer Disinfector	STERILMED	WD-6 (customized model- large capacity) WD-8 WD-10 WD-12 WD-15 WD-18	35424	42281508	IIb

Classification : IIb (According to MDD, Annex IX – Excluding Section 4)
meet the provisions of the following EC Council Directives and Standards. All supporting documentation's are retained under the premises of the manufacturer and the notified body.

Directives : Medical Device Directive (MDD 93/42/EEC), Annex II (Excluding Section 4) and 2007/47/EC Annex 2.3 requirements. MDD 93/42/EEC and 2007/47/EC Annex 2.3 (Excluding conformity assessment route Annex 4)

Standards : Standards applicable to this product are EN 15883-1:2009 , EN 61326-1:2021, EN 61010-2-040:2021, ISO 13485:2016, EN ISO 9001:2015, EN ISO 14001:2015, 15223-1:2021

Notified Body : UDEM International Certification Auditing Training Centre Industry and Trade Co.
Mutlukent Mah. 2073. Sok. (Eski 93. Sok) No: 10 Çankaya / ANKARA / TURKEY

Burhan ZORLU

Company Manager

28.02.2024

Expiry Date: 26.09.2028 / Revision: 2023.08

UDEM 2292