



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

Devices Directive

DECLARATION OF COMFORMITY

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 products mentioned below:

Product : Steam Sterilizer
GMDN Code : 38671
Model Code :

Product	Brand	Model	GMDN Code	UNSPSC Code	Class
Steam Sterilizer	SMA SMB	DSD -160, DSD -200, DSD-250, DSD-300B, DSD-300, DSD-450, DSD-540, DSD-675, DSD-810, DSD-945, SSD-160, SSD-200, SSD-250, SSD-300B, SSD-300, SSD-450, SSD-540, SSD-675, SSD-810, SSD-945, VD-160, VD-200, VD-250, VD-300B, VD-300, VD-450, VD-540, VD-675, VD-810, VD-945, VD-75	38671	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 ISO 13485:2016, EN ISO 14971 :2019, EN ISO 15223-1:2021, EN ISO 80601-2-56:2017/A1:2020, EN 60601-1-2:2015/A1:2021, EN 60601-1-6:2010/A2:2021, EN 60601-1:2006/A2:2021, EN 60601-1-8:2007/A2:2021, EN 60601-1-11:2015/A1:2021, EN IEC 61000-4-3:2020, EN 62304:2006/A1:2015, EN 62366-1:2015/A1:2020

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

04.08.2023

Expiry Date: 26.08.2028 / Revision: 2023.08

UDEM 2292