




DECLARATION OF CONFORMITY

We declare that, these products which belong to "AKMEDA MEDİKAL" company under our responsibility also produced and checked according to the requirements of 93/42/EEC

Manufacturer : Akmeda Medikal Danışmanlık Gayrimenkul Turizm Sanayi Ve Ticaret Limited Şirketi
Office Address : Ostim OSB Mah. 1212.Cadde No:2 Yenimahalle / Ankara / Turkey
Production Address. : Ostim OSB Mah. 1212.Cadde No:2 Yenimahalle / Ankara / Turkey
Sterilization Address : Ostim OSB Mah. 1212.Cadde No:2 Yenimahalle / Ankara / Turkey
Storage Address. : Ostim OSB Mah. 1212.Cadde No:2 Yenimahalle / Ankara / Turkey
Phone : +90 312 354 22 22 **Fax** : +90 312 354 22 78
Web: www.akmeda.com **E-Mail:** info@akmeda.com

Product Name : Sterile Disposable Surgical Gowns, Drapes and Drape Sets (TD-COS-2)

Product Types: Medicotex Sterile Disposable Surgical Gowns, Drapes and Drape Sets (TD-COS-2) 

Class of Product : Class Is Rule I

GMDN Code / GMDN Name : 47783 General-purpose surgical drape, single-use, sterile. Intended purpose.
35778 Disposable , Surgical Apron

Intended Purpose : It is used as a barrier against bacterial agents which maybe a factor in the development of surgical field infections for the environment, equipment and the sterile condition of the patient to be maintained during the surgical conditions.

Applicable Harmonized Standards And Directives: Harmonized Standardlist is referenced. Sterile Disposable Surgical Gowns, Drapes and Drape Sets Harmonized Standarts (TD-COS-8).
Harmonized standards:

TS EN ISO 15223-1: 2016, TS EN ISO 13485: 2012, TS EN ISO 13485: 2016, TS EN ISO 14971, MEDDEV 2.4/1 Rev 9 , MEDDEV 2.7/1 Rev 4 , MEDDEV 2.12/ 1 Rev 8, EN 1041:2008+A1, 93/42/EEC, TS EN ISO 14937, EN ISO 10993-1, TS EN ISO 10993-5, TS EN ISO 10993-7, TS EN ISO 10993-10, ISO 10993-12, TS EN 868-5, EN 62366-1, TS EN 13795+A1, EN ISO 22612, EN ISO 22610, EN ISO 11737-1, EN ISO 9073-10, TS 257 EN 20811/T1, EN ISO 13938-1, EN 29073-3, TS EN ISO 14644-4, TS EN ISO 14698-1, TS EN ISO 14644-5, TS EN ISO 14644-6, TS EN ISO 14644-14, TS EN ISO 14644-10 , TS EN ISO 14937, TS EN ISO 14644-2, TS EN ISO 14644-3, TS EN ISO 14698-1, TS EN ISO 14698-2

Doc. No:TD-COS-4 Pub. Date : 21.08.2017 Rev. No: 02 Rev. Date: 06.09.2018

Conformity Assesment Route : MDD (93/42/EEC) ANNEX V- Section3

Name of Notified Body : UDEM International Certification Auditing Training Centre
Industry and Trade Inc. Co.
Address of Notified Body : Mutlukent Mahallesi 2073 Sokak(Eski 93.Sokak) No:10
Çankaya / Ankara / Turkey
Phone: + 90 (312) 443 03 90 **Fax:** +90 312 443 03 76

Initial Date of CE Marking : 04.04.2018

Expiration Date of CE Marking : 03.04.2023

CE Certificate No: M.2018.106.9500

Initial Date of Decleration of Conformity: 20.04.2018

Expiration Date of Decleration of Conformity: 03.04.2023

Place and Release date of CE Marking:  2292 – ANKARA / TURKEY 04.04.2018

- **Declaration of Conformity for Human Blood Derivative**
We declare that our products don't contain human blood derivative. (93/42/EEC)
- **Declaration of Conformity for Animal-derived Tissue**
We declare that our products don't contain animal-derived tissue. (2003/32/EC, 93/42/EEC)
- **Declaration of Conformity that doesn't contain Drug**
We declare that our products don't contain drug (93/42/EEC)
- **Declaration of Conformity that doesn't contain Phthalate**
We declare that our products don't contain Phthalate.(93/42/EEC)
- **Declaration of Conformity that doesn't contain Natural Latex**
We declare that our products don't contain natural latex. (Natural Rubber Latex Allergy; Adopted 27 June, 2000. Doc.SANCO/SCMPMD/2000/0009 Final, 93/42/EEC)

Product List is in Appendix

ŞENOL AKARŞU
General Manager

AKHEDA MEDİKAL DANIŞMANLIK
GAYRİMENKUL VE TİC. SAN. VE TİC. LTD. ŞTİ
Ostim Osb. Mah. 12/2. Cad. No 2 Yenimahalle / ANKARA
Ostim V.D. 032 020 0657 Tic. Sic. No : 39927
Mersis No : 0032029065700015

Doc. No:TD-COS-4 Pub. Date : 21.08.2017 Rev. No: 02 Rev. Date:06.09.2018