



INTERNATIONAL FIRST CERTIFICATION
CERTIFICATE OF CONFORMITY

We hereby declare, Manufacturer, Distributor/EU Representative:

APEX TEKSTIL ve SAGLIK URUNLERI SANAYI TICARET LIMITED SIRKETI

Acidere OSB Mahallesi Ordu Caddesi No:23 Saricam / Adana/Turkey

that the following described product in our delivered version complies with appropriate basic safety and health requirements of the 93/42/EEC Medical Device Directive (Anex VII) based on its design and type, as brought into circulation by us In Case of the alteration of the product, not agreed upon by us, this declaration will lose its validity.

Description of the Product	: Disposable gowns
Model of Product	: X-Ray, Patient, Surgery, Visitor / Standard, Hooded
Product Commercial Brand	: AMET
Applicable EC Directives	: 93/42/EEC Medical Device Directive
Harmonized Standards	: EN 13795-1, EN 15223-1, EN ISO 14971 : EN ISO 10993-1
Classification	: Class I Anex VII (Non-Sterile)
GMDN Kodu	: 35778

Issue date	: 06.05.2020
Valid from	: 06.05.2020
Valid till	: 05.05.2021
Certificate Number	: MCE.20.315

System Certificate Approved



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