

DECLARATION OF CONFIRMITY

Acc.; 93/42/EEC



Name of Product : Operation Table (GMDN #: 42308)

Model No : ATESE ET 300 Series

Serial No : 2000119

Description of Product : Electromechanically controlled Operation Table

UNSPSC Code : 42192002 General Propose medical operation table

Steril : No

Classification / Rule (MCD - Ek IX'ye göre) : Class I

Harmonized Standards : ISO 60601-2-46 ; EN ISO 14971; EN 1041; EN ISO 13485; EN ISO 17510-1; EN 60601-1:2006/AC:2014; EN 60601-2-46, ISO 14155:2011

Notified Body / CE Certificate No : ELDAS REPORT NO 06017-01

Declaration :

- ATESE Sağlık Hizmetleri Limited Şirketi declares that the above product to which this declaration relates, bears the CE Marking, and is in conformity with the applicable requirements of the Council Directive MDD 93/42/EEC of 14 June 1993, concerning medical devices, which allows its free distribution, sale and circulation in EEC.
- All supporting documentation is retained at the manufacturer's premises

The present EC Declaration of Conformity is applicable to all mentioned medical devices, manufactured by ATESE Sağlık Hizmetleri Sanayi ve Ticaret Limited Şirketi, Ankara, Turkey, and/or anyway realized under the Manufacturer's Certified Quality System control for a period of about 1 year from the approval date of the present document.

On Behalf of, ATESE Sağlık Hizmetleri Sanayi ve Ticaret Limited Şirketi

Date : 24.04.2017

Signature

Quality Management Representative

Mehmet İlker Şahin

Hüseyin Batı

General Manager

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