

Üretici:

ATESE SAĞLIK HİZMETLERİ LTD.ŞTİ.
İVÖĞSAN 22 Cd. 1462 Sk. No: 16. Yenimahalle / Ankara / Turkey
Tel: +90 312 394 45 67
info@atese.com.tr

Doküman No ve Revizyon No

DoC001-07

DECLARATION OF CONFIRMITY

Acc.;93/42/EEC



Name of Product : SurgicalLight(GMDN #: 12282)
Model No : ATESE LED 700 Series
Serial No : G0780
Description of Product : Touch panel, LED surgical lighting
UNSPSC Code : 42191602 Operating room lighting and accessories
Steril : No
Classification / Rule : Class I
(MCD-EklX'ye göre)
Harmonized Standards : EN 60529; EN ISO 14971; EN 1041; EN ISO 13485; EN ISO 17510-1; EN 60601-1:2006/AC:2014; EN 60601-2-31/A1, ISO 14155:2011
Notified Body/ CE Certificate No : ELDAS REPORT NO 07017-01

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 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 Ticaret Limited Şirketi'

Date 24.04.2018

Signature

Quality Management Representative

Mehmet İlker Şahin

Hüseyin Batı

General Manager

ATESE
ATESE Sağlık Hizmetleri Şti.
İvöğsan Özi Anadolu Sanayi Sitesi 22. Cad.
1462 Sok. No: 16 İvöğsk - Östüm / ANKARA
Tel: (0312) 394 45 67 Fax: (0312) 394 45 90
Müş. Vergi Dairesi. 001 042 08:18