



EC DECLARATION OF CONFORMITY

We,
ALMI MEDİKAL VE ÖZEL SAĞLIK HİZMETLERİ LTD.ŞTİ

here with declare that *Sterile and non sterile surgical drapes gowns and sets* for
medical use

Disposable Surgery Drape Gown and Surgery Sets
are produced in our manufacturing place,

Factory Address :

Anbar Mah. Demirciler San. Sit. 22. Cad. No:15 Kayseri/TURKEY

Tel : 0 352 311 30 75 - Fax : 0 352 311 30 85

E-mail: almi@almedmedical.com

[www. Almedmedical.com](http://www.Almedmedical.com)

According to harmonize standards,

EN ISO 9001:2015 EN ISO 13485:2016, EN ISO 14971:2013, EN ISO 13795-1:2013, EN ISO
11607-1:2014, EN ISO 11607-2: 2010, EN 15223:2013, EN 1041:2014, EN ISO 11135-1:2014 EN
ISO 14644-1: 2016, EN ISO 14644-2:2016, , EN ISO 14644-7:2004, EN ISO 10993-1:2007, EN 556-
1:2001, ISO 14155:2011

93/42/EEC Annex V Production Quality Assurance System.

Product Classification: Class I Sterile (93/42/EEC Annex V, Rule 1)

Issued Date : 10.01.2018

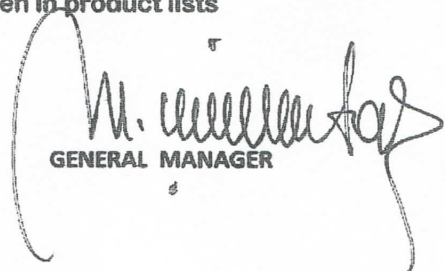
Valid Date : 10.01.2020

The first product date is with CE Marking: 25.01.2011 – Eye Drape With Single Poch

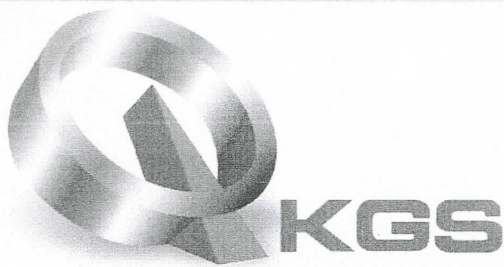
GMDN Kode:

4643,46416,46697,61371,39320,42559,40511,47781,47048,47451,45021,47447,47783,1568743
970,16006,15778, 7450, 37456, 11902,35091,35492,32170,35778,40503, 40511, 47782, 35625,
35551,35180,35181, 35651,38497,32071, 15643, 16474, 44090, 44093, 44318,44059, 44060,
45148, 45146,44052,44053

Products: All product types given in product lists


GENERAL MANAGER





QUALITY SYSTEM CERTIFICATE

This is to Certify that the Quality Management System of

ALMI MEDİKAL VE ÖZEL SAĞLIK HZ. LTD. ŞTİ.

Anbar Mah. Demirciler San.
Sitesi 22, CAD. No: 15
Melikgazi/Kayseri.

has been assessed by **KGS Certification Sdn. Bhd.**
and found to comply with

ISO 13485:2016

for the scope **Medical Devices Quality Management System**

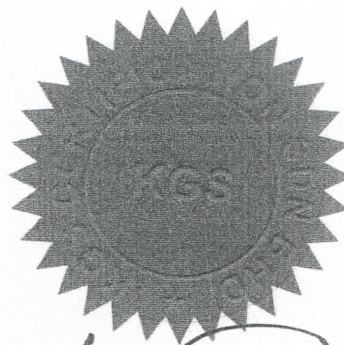
Disposable operating surgical coating, prevent and sets production

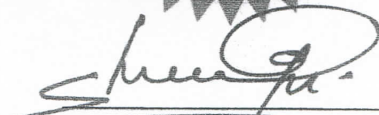


Certificate No : **110545**
Date of Initial Certification : **17 January 2018**
Date of Issue/Reissue : **17 January 2018**
Renewal Due : **16 January 2021**



MDQMS 15102014 CB 01




Authorized Signatory

This certificate is subject to the company maintaining its system to the required standards, which will be monitored by KGS.
The use of this Certificate and the KGS Certification / Accreditation Mark are subject to the Regulations Applicable to Holders
of KGS Certification Sdn. Bhd.

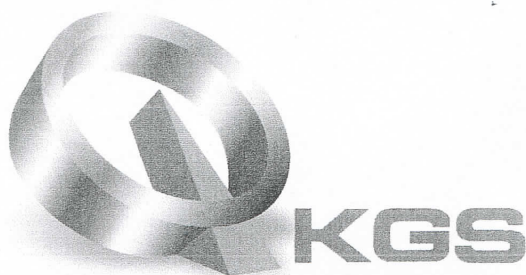
KGS Certification Sdn. Bhd. (824092-A)

No. 15, Lorong BLM 6/4, Bandar Laguna Merbok, 08000 Sungai Petani, Kedah Darul Aman, Malaysia.

Tel: 604 441 1524 Fax: 604 441 0610 Email: kgs-certification@gmail.com

www.kgscert.com

The Certificate remains the property of KGS and shall be returned when requested. It may only be reproduced in its entirety and without change.



QUALITY SYSTEM CERTIFICATE

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ALMI MEDİKAL VE ÖZEL SAĞLIK HZ. LTD. ŞTİ.

Anbar Mah. Demirciler San.
Sitesi 22, CAD. No: 15
Melikgazi/Kayseri.

has been assessed by **KGS** Certification Sdn. Bhd.
and found to comply with

ISO 9001:2015
Quality Management System

for the scope

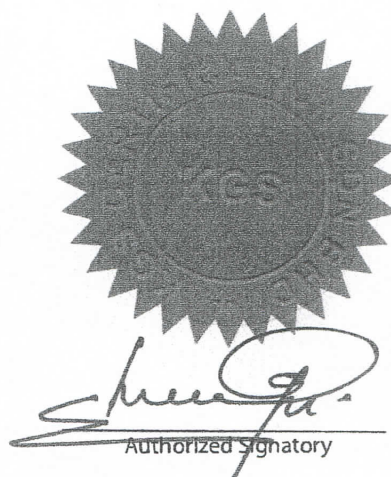
Disposable operating surgical coating, prevent and sets production



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QS 18042014 CB 15



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KGS Certification Sdn. Bhd. (824092-A)

No. 15, Lorong BLM 5/4, Bandar Laguna Merbok, 08000 Sungai Petani, Kedah Darul Aman, Malaysia.

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