CAPULUS
Medical Services+

OUR RESPONSIBILITY FOR YOUR HEALTH

SURGICAL GOWNS
CE/FDA CERTIFICATION
SHIPPING PACKING MEASUREMENTS

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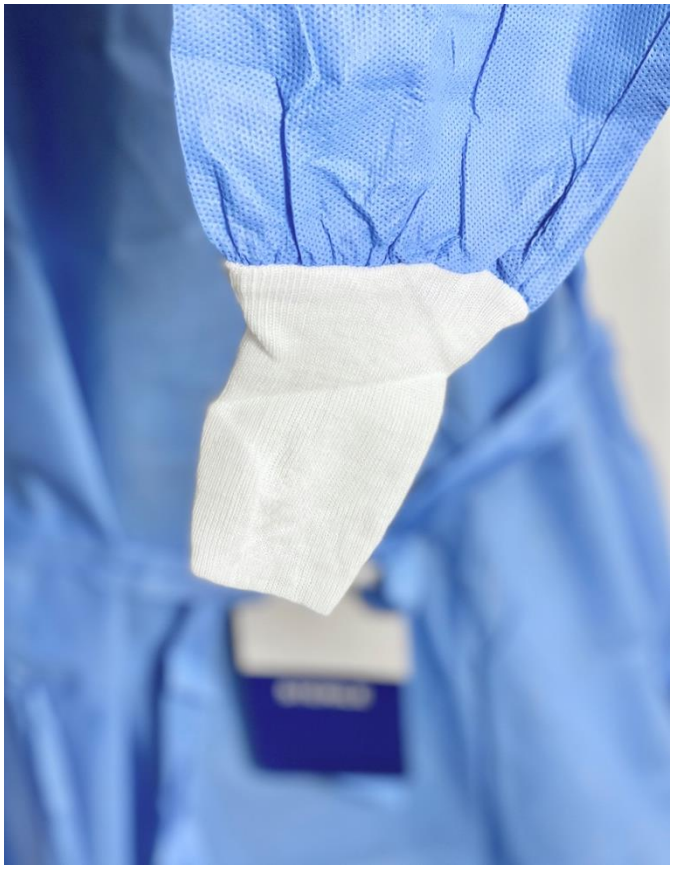

SURGICAL GOWN
CE CERTIFICATION

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q6 083528 0010 Rev. 00

Holder of Certificate: [redacted]

Facility(ies): [redacted]

Certification Mark:

Scope of Certificate: Production and Distribution of Surgical Set, Surgical Gown, Surgical Drape, Tube Cover, Liquid Collection Pouch, Protective Gown, Warm Blanket and Surgical Hood

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1978307

Valid from: 2019-04-01
Valid until: 2022-03-31

Date, 2019-04-01

Stefan Preiß

Page 1 of 1
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

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SURGICAL GOWN
FDA CERTIFICATION

Fiscal Year 2020

CERTIFICATION OF REGISTRATION

This certifies that:

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through

Owner/Operator

Device Listing#:

CTB will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. CTB makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. CTB assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. CTB is not affiliated with the U.S. Food and Drug Administration.

CTB FDA

Chief engineer
Issued: March 4, 2020
Expiration Date: December 31, 2020

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PACKAGING MEASUREMENTS

产 品 代 码: JKJ0001Y2015
Product Code: JKJ0001Y2015

产品名称：一次性使用手术衣(35g普通型手术衣L号)
Product Name：Disposable Surgical Gown L(35g)

ARUIKON®
艾锐康

生产许可证: 豫食药监械生产许 20150081号
License No.: 豫食药监械生产许 20150081号

注册证编号: 豫械注准20172640918
Certificate Code: 豫械注准20172640918

数　　量/QTY:	64psc
生产日期/MFG DATE:	20200401
生产批号/Lot No.:	20200401
有效期/EXP DATE:	三年/3 years
净　　重/N. W.:	5.7kg
毛　　重/G. W.:	7.2kg
箱规/Carton Size:	50x40x45cm

一次性使用　CE 0123　STERILE EO 环氧乙烷灭菌

河南洁利康医疗用品有限公司
河南省平顶山市鲁山县产业集聚区南区新兴路

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