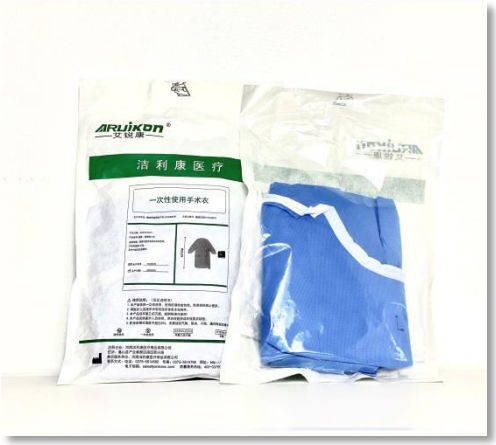
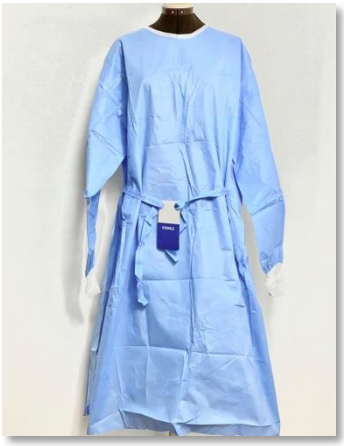
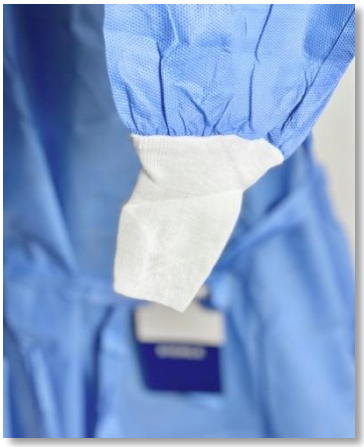
PRODUCT SHEET







Product	Arvikon Grown sterile single use
Article Nr.	CAP-med-s-020
Packaging Unit	1/1 single packed – 60/60 box carton (English language branded)
Material / in g thickness	35g, poly propylene (PP)
Colour / Sizes	Blue or green – M / L / XL
Certification	CE (TÜV SÜD) Notified Body Identification-Nr. 0123, CFDA, ISO 13485 and EN 13795 certified
Protection Class	Protection class 3, 99,9% high bacterial filter efficiency
Scope of Application	All applications in the ward and surgical area
Dimensions / weight	50x40x45 in cm (HxBxD), 7,2kg carton

Sizes	**M**	**L**	**XL**	**Tolerance**
Dimensions / cm	145	150	150	+/-2 cm

CAPULUS assumes no guarantee / liability for topicality, correctness and completeness of the information and data provided by the manufacturer. The product may differ from the above picture.

Contact / Order:

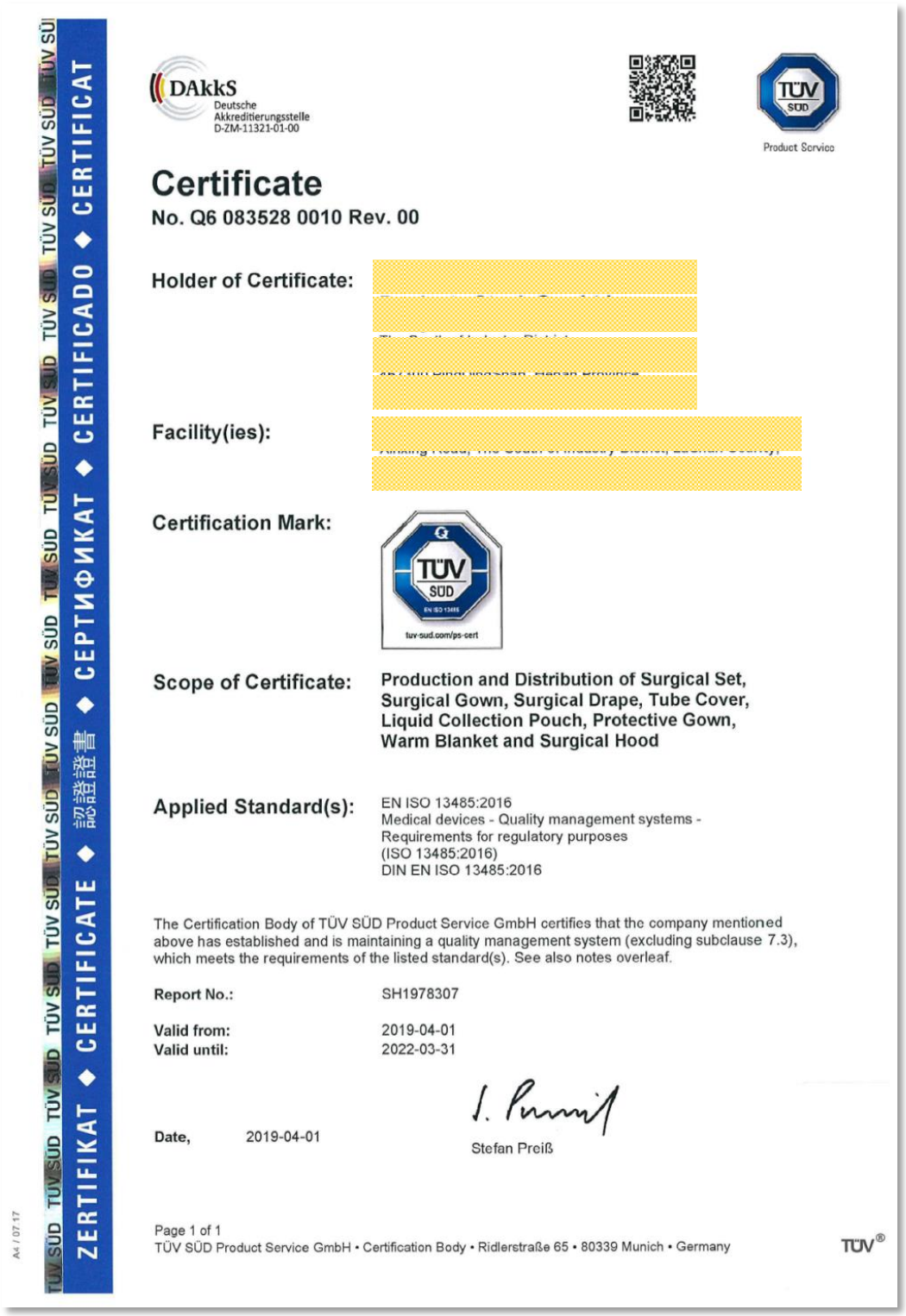
Tel: +49 40 307 772 15

E-Mail: info@capulus-services.de

Request: Inquiry Form Business Customer

Internet: CAPULUS Medical Services

CERTIFCATE



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

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

TÜV SÜD Product Service

Certificate

No. Q6 083528 0010 Rev. 00

Holder of Certificate:

Facility(ies):

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

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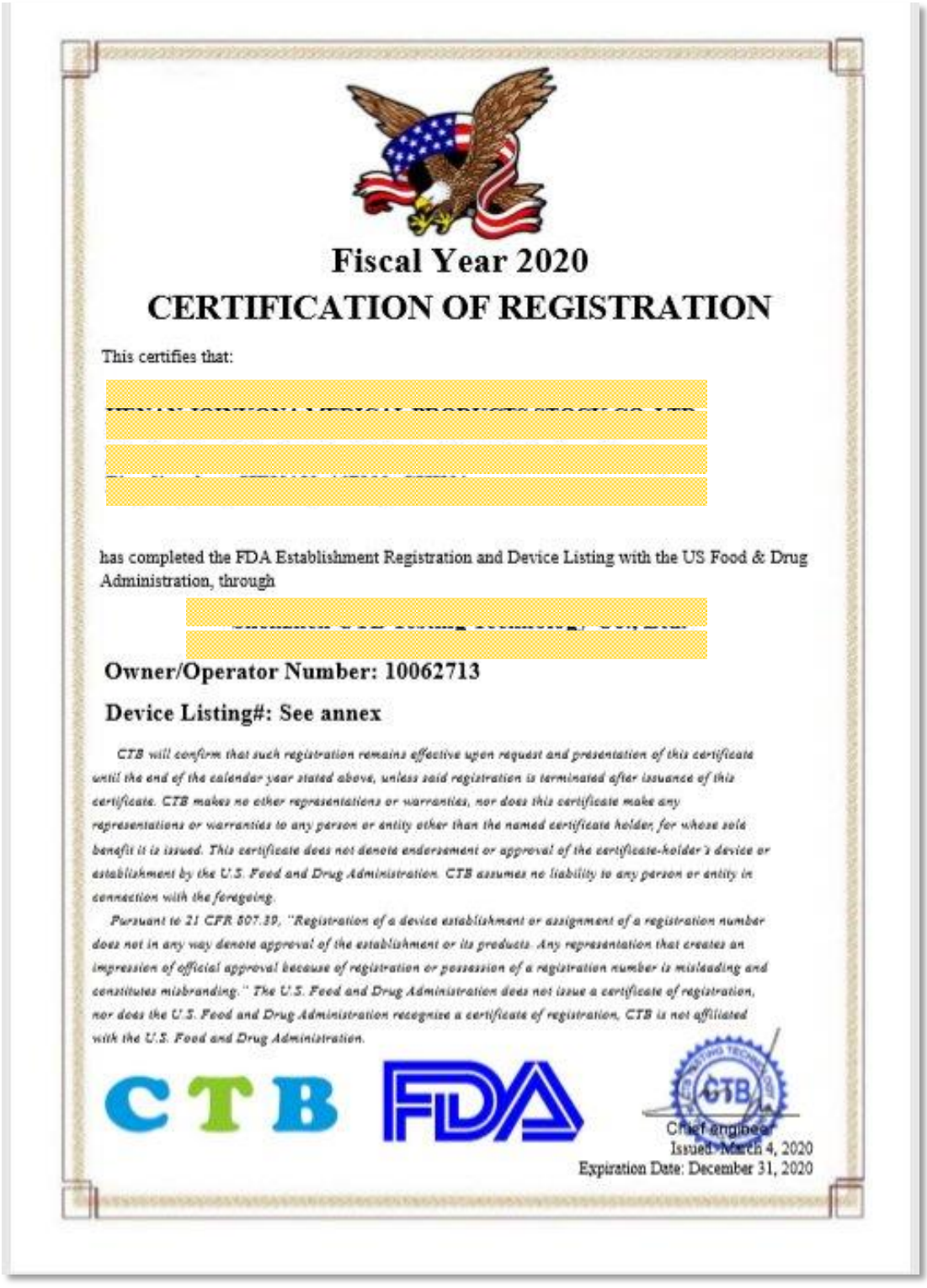
CERTIFCATE



Fiscal Year 2020

CERTIFICATION OF REGISTRATION

This certifies that:

[redacted]

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

[redacted]

Owner/Operator Number: 10062713

Device Listing#: See annex

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