



Certificate

No. Q5 038951 0011 Rev. 02

Holder of Certificate: **AESCULAP CHIFA Sp. z o.o.**
ul. Tysiaclecia 14
64-300 Nowy Tomysl
POLAND

Certification Mark:



Scope of Certificate: Design, development, production, distribution and servicing of surgical instruments.
The provision of manufacturing services for vascular and surgical products and related surgical vascular accessories.
The provision of servicing and distribution services for medical devices.
The provision of ETO sterilization for medical devices.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 038951 0011 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_038951_0011_Rev.02)

Report No.: 713197184

Valid from: 2021-05-03

Valid until: 2023-10-31

Date, 2021-05-03



Christoph Dicks
Head of Certification/Notified Body

Certificate

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

Facility(ies): AESCULAP CHIFA Sp. z o.o.
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ul. Budowlanych 1a, 21-300 Radzyn Podlaski, POLAND

Production of surgical instruments.

Parameters: ./.

Supplement to Quality System Certificate

No. SUP 038951 0013 Rev. 00

This supplement is only valid in conjunction with the main certificate: **Q5 038951 0011 Rev. 02**

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The quality system certified as stated in the main certificate additionally fulfills the applicable requirements of

EN ISO 11135:2014 Sterilization of health care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices.

Audit Report: 713197184

Dated: 2019-09-15

The assessment was performed by auditors authorized under TÜV SÜD Product Service GmbH procedures. The audit team included an auditor authorized for sterilization

Valid from: 2021-05-03



Christoph Dicks
Head of Certification/Notified Body