





Certificate

No. Q5 038951 0011 Rev. 04

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 metal components.

The provision of manufacturing services for vascular and surgical products and related surgical vascular accessories.

The provision of manufacturing services for configured customized sets.

The provision of special coating with medicinal products and animal origin material for medical devices.

The provision of manufacturing services for implants for replacement of connecting tissue.

The provision of manufacturing services for local haemostatic agent and accessories for suturing techniques.

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. 04

Report No.: Valid from: Valid until:

Date,

2023-10-05

713298530 2023-11-01 2026-10-31

Christoph Dicks Head of Certification/Notified Body





Certificate

No. Q5 038951 0011 Rev. 04

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.

ul. Tysiaclecia 14, 64-300 Nowy Tomysl, POLAND

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The provision of servicing and distribution services for medical devices.

The provision of ETO sterilization for medical devices.

Aesculap Chifa Sp. z o.o.

ul. Budowlanych 1a, 21-300 Radzyn Podlaski, POLAND

Production of surgical instruments and metal components.

Parameters: ./.