

QUALITY INSPECTION CERTIFICATE

Cert.-No.: 1- 040710 | February 13, 2023

Aesculap AG certifies, that
our products and raw materials

are designed, manufactured and tested according defined and documented specifications and procedures.

The following national and international standards and requirements were met:

- ☒ EN ISO 13485:2016
- ☒ EN ISO 9001:2015
- ☒ EU Regulation 2017/745 on Medical Devices
- ☒ Council Directive 93/42 EEC of 14. June 1993 concerning Medical Devices
- ☒ ISO 7153-1 (Surgical Instruments-Metallic materials; Part 1: Stainless steel)
- ☒ Others: ISO 7151 Surgical Instruments - Non cutting articulated instruments, General requirements and test methods (hardness: 42-50 HRC).
ISO 7741 Instruments for surgery - Scissors and shears General requirements and test methods (hardness: 50-58 HRC).
ISO 7740 Instruments for surgery; Scalpels with detachable blades; Fitting dimensions
ASTM Designation: A 380 Standard Practice for Cleaning, Descaling and Passivation of Stainless Steel Parts, Equipment and Systems
ASTM Designation: A 967 Standard Specification for Chemical Passivation Treatments for Stainless Steel Parts
ASTM Designation F 899 Standard Specification for Wrought Stainless Steels for Surgical Instruments
DIN EN ISO 13402 Surgical and dental hand instruments. Determination of resistance against autoclaving, corrosion and thermal exposure
DIN EN 10088-1 Stainless steels - Part 1: List of stainless steels;
DIN EN 10088-2 Stainless steels; Technical delivery conditions for general purpose sheet/plate and strip
DIN EN 10088-3 Stainless Steels - Part 3: Technical delivery conditions for semi-finished products, bars, rods, wire, sections and bright products of corrosion resisting steels for general purposes
DIN 96298 Medical Instruments -Part 1-3 : Terms, Measurement Methods and Testing

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