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INSPECTION CERTIFICATE / CERTIFICATE OF ANALYSIS

AESCULAP AG certifies that the product inspection according to defined and documented specifications and procedures were done for Aesculap Surgical Instruments.

All requirements of relevant and applicable national and international (ISO) standards are met.

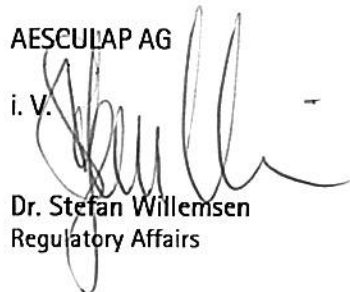
The products are manufactured and tested according to defined and documented specifications and procedures.

In particular the following national and international standards and requirements were met:

- | | | |
|-------------------------------------|---|--|
| <input checked="" type="checkbox"/> | EN ISO 13485:2016 | |
| <input checked="" type="checkbox"/> | Council Directive 93/42 EEC of 14. June 1993 concerning Medical Devices | |
| <input type="checkbox"/> | EN ISO 11135 et seqq. | (Validation and routine control of ethylene oxide sterilization) |
| <input type="checkbox"/> | EN ISO 11137 et seqq. | (Validation and routine control of radiation sterilization) |
| <input checked="" type="checkbox"/> | ISO 7153-1 | (Surgical Instruments-Metallic materials; Part 1: Stainless steel) |
| <input type="checkbox"/> | ISO 5832 series | (Implants for surgery - Metallic materials) |
| <input type="checkbox"/> | ISO 5834 series | (Implants for surgery - Ultra-high-molecular-weight polyethylene) |
| <input type="checkbox"/> | ISO 6474 series | (Implants for surgery - Ceramic materials) |
| <input checked="" type="checkbox"/> | Technical / physical | (please see below for details if applicable) - passed test |
| <input type="checkbox"/> | Chemical | (please see below for details if applicable) - passed test |
| <input checked="" type="checkbox"/> | Others: EN ISO 17664 | (Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices) |

AESCULAP AG

i. V.


Dr. Stefan Willemsen
Regulatory Affairs

i. A.


Dr. Thomas Seitz
Regulatory Affairs**Chairman of Supervisory Board:**
Prof. Dr. Heinz-Walter Große**Executive Board:**
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(Chairman)
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(Deputy Chairman)
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Tests	Inspection criteria	Results
Identity Visual inspection according to the order and drawing	Prevent the trouble by incorrect papers	passes test
Surface Visual inspection of the product	No defects, smooth surface	passes test
Label / Product Marking Visual inspection according to specification	Correct Information on product, label and delivery papers	passes test
Quantity balance Visual inspection of manufacturing paper	Number of manufactured pieces corresponds to order	passes test
Dimensions / Sizes Checking of main dimensions according to engineering drawing	Verify whether the measurements of product is as required	passes test