



Management System
EN ISO 13485:2016
ISO 9001:2015

www.tuv.com
ID 9105070670

ritter MEDICAL

Certificate of Conformity for Robotic Tips, sterile

Article number: 49xxx-xxxx
Article name: xxx
Material: PP
Lot no.: xxxxxx/x
Production date: month year
Expiry date: month year



To assure that this product has passed all relevant quality inspections, the company Ritter is in accordance with and certified to the current valid ISO 9001 / EN ISO 13485, and has introduced and applied a quality system. Following these guidelines, the proof of fulfilment of the above-mentioned standard has been provided by the certification through TÜV Rheinland.

Ritter certifies that these robotic tips are manufactured by state of the art processes, quality control procedures, raw materials, final inspections and meet all required specifications in accordance to test n° 890,891, 892, and 893. For special applications, appropriate methods and means, they must be verified and validated. An independent laboratory has tested the product to be free of human DNA, DNase, RNase, PCR inhibitors, ATP and endotoxins with the following purity specifications:

Human DNA:

- Human DNA free => samples will show no evidence of human DNA with a detection level of < 0.5 pg/µl.

DNase:

- DNase free => samples will show no evidence of DNase with a detection level of < 7.1 x 10⁻⁵ units.

RNase:

- RNase free => samples will show no evidence of RNase with a detection level of < 1 x 10⁻⁹ KunitzU.

PCR inhibitors:

- PCR inhibitors free => samples will show no detection level.

ATP:

- ATP free => samples will show no evidence of ATP with a detection level of < 10⁻¹² mmol/µl.

Endotoxins: Ph. Eur. 2.6.14 Method C

- Endotoxin free => samples will show no evidence of endotoxin with a detection level of < 0.02 EU/ml.

bioclean® / sterile:

- Product treatment by use of E- Beam in accordance with EN ISO 13485.

Schwabmünchen, 2020-09-14

Stephan Schatz
COO

Ritter GmbH
Kaufbeurer Str. 55
D-86830 Schwabmünchen

Tel.: +49 8232 50030
Fax: +49 8232 500310
Internet: www.ritter-medical.de