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PN1058605-01 Rev A

March 13, 2019

Klaus Roth
SMP GmbH
Hachinger Strasse 262
72072 Tübingen, Germany

Subject: SMP GmbH: EndoWrist® Instrument Cleaning Efficacy Studies

Dear Mr. Roth:

Intuitive Surgical recognizes that SMP GmbH performs cleaning efficacy studies in compliance with AAMI TIR 30:2011, EN ISO 15883-1: 2014, DGKH, DGSV, AKI and Robert Koch Institute.

Starting 2015, SMP performs cleaning efficacy studies that are consistent with Intuitive Surgical's test protocols for cleaning efficacy for the following Intuitive devices:

- Xi™ 8mm da Vinci® EndoWrist® Instruments
- Xi Single-Site® EndoWrist Instruments
- Xi da Vinci EndoWrist Staplers 30 and 45
- Xi 8mm Endoscope
- Si™ 8mm da Vinci EndoWrist Instruments
- Si Single-Site EndoWrist Instruments
- Si 5mm da Vinci EndoWrist Instruments
- Si da Vinci EndoWrist Stapler 45

Intuitive Surgical acknowledges that SMP GmbH is an accredited testing laboratory by DAkkS according to DIN EN ISO / IEC 17025:2005, guidelines 93/42/EEC and 90/385/EEC and we recognize that test results support the use of the equipment SMP has validated to clean the EndoWrist devices listed above.

Sincerely,



Veronica Thralls
Sr. Director, Device Validation & Applied Sciences
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