

# Confirmation

## SMP GmbH

Prüfen Validieren Forschen

Hechinger Straße 262  
72072 Tübingen - Germany

has tested a cleaning process for the master products of the following instrument family

### **IS4000 (XI) 8MM BASIC INSTRUMENTS\***

manufactured by  
Intuitive Surgical, Inc.  
1266 Kifer Road, Sunnyvale, CA 94086 - USA

using automated pre-cleaning in  
MedUSE 60-F SiXi E/M REF: 5641 SN: 20200813-0001  
with a dedicated Load Carrier for DaVinci Xi Instruments (REF: 1.19102)

manufactured by  
Medisonics AG  
Weststr. 115  
CH 8408 Winterthur - Switzerland

using the washer-disinfector  
Uniclean PL II 15-2 FD/EL (No. 4) SN: B180824 at Universitätsspital Zürich, Logistik-Zentrum, Zürcherstrasse 123  
8952 Schlieren/ZH  
with a dedicated Load Carrier for DaVinci Instruments (REF: 010548428)

manufactured by  
MMM Münchener Medizin Mechanik GmbH  
Sammelweisstraße 6  
82152 Planegg - Germany

and a dedicated Cleaning Program

and the detergent  
Mediclean forte – REF: 405033  
manufactured by  
Dr. Weigert GmbH & Co. KG  
Mühlenhagen 85 20539 Hamburg - Germany

Based on the test results achieved in the cleaning examinations with the project number 20321 SMP GmbH declares that the acceptance criteria for successful cleaning as defined by the sponsor were fulfilled for the instrument family listed above. The investigations were performed according to the protocols and instructions provided by Intuitive Surgical and named in the reports. The following acceptance criteria were met:

- After cleaning no residual contamination was visible
- The total amount of residual protein was lower than 100 µg/sample
- The total amount of residual hemoglobin was lower than 2.2 µg/cm<sup>2</sup>

Tübingen,

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Dr. Ludger Schnieder  
President/CEO

\* The design of the IS4000 (Xi) 8mm Basic Instruments is equivalent to the IS2000/IS3000 (Si) 8mm family of instruments (with the exception of the orientation of the components within the housing). Therefore, the master products of the IS4000 (Xi) 8mm Basic Instrument family also serve as the master products for the IS2000/IS3000 8mm Instrument family.