



Labor für medizinische Materialprüfung GmbH

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# Certificate Biocompatibility

**Test material:** **Bandage scissors, Scissors and Forceps  
Single use instruments, coated with  
Vestosint®1141 coloured Polyamide 12 fluidized  
bed coating powder.**

**Manufacturer:** **Si US Instruments GmbH  
Kanalstraße 4-6, 13599 Berlin**

**Studies performed:** **The following studies were performed in  
order to determine the biocompatibility of  
the test material according to DIN EN ISO  
10993-1:2010, DIN EN ISO 10993-5:2009  
and DIN EN ISO 10993-12:2012.**

**Cytotoxicity after direct cell contact**

**Report:** **B0337/14**

**Results:** The different test materials showed no relevant  
cytotoxic effect after direct cell contact and  
fulfilled the requirements of DIN EN ISO 10993-  
5:2009.

**Single use instruments, coated with  
Vestosint®1141 coloured Polyamide 12  
fluidized bed coating powder, are non  
cytotoxic and biocompatible based on the  
field of cytotoxicity for medical devices  
using contact duration period  $\leq$  24 h.**

**Date:** **August 30, 2014**

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**Dr.-Ing. Ute Müller**  
Manager Biological Safety Testing

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