

## To Whom it may concern:

As part of its risk management, Bodypoint has conducted cytotoxicity tests by MEM Extraction Cytotoxicity Assay, in accordance with the requirements of <u>ISO 10993-1 Biological evaluation of medical devices</u>, <u>Part 1: Evaluation and testing within a risk management process</u>.

## We certify that the following Flex-shaft Joystick Handles are Non-Cytotoxic:

PC101A/B 3" Ergonomic U-Shaped PC102A/B 4" Ergonomic U-Shaped C" Florida (" F

PC104A/B 6" Flex-Shaft
PC107A/B Domed Rubber
PC110A/B Mushroom-shaped

## Note:

The above models of joystick handle are made using identical materials and processing to those included in our testing. Copies of these tests are available on request:

Bodypoint Joystick Handles (PC101 and PC102) Cytotoxicity ISO Assay Final Report.pdf
Bodypoint Joystick Handles (PC107 and all Flex-shafts for additional models) Cytotoxicity ISO Assay Final
Report.pdf

The flexible shaft which serves as the base for all Bodypoint Flex-shaft Joystick Handle products is proven Non-Cytotoxic. The models listed below include additional components for their affixed tops—these are considered to be low-risk because of the use of market-proven, inert materials and processing, but have not been individually tested for cytotoxicity:

PC103A/B Ball Knob

PC108AS/BS Mushroom Head Small Rubber
PC108AL/BL Mushroom Head Large Rubber

PC109A/B-BLUE Aluminum Top, Blue

**Matthew Kosh** 

Signed Matthew holl Date 5/15/2018

President

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