



Certificate of Conformance

ISO 10993-5: Biocompatibility (Cytotoxicity)

As part of its risk management, Bodypoint has verified the biocompatibility of its products in accordance with the requirements of **ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro Cytotoxicity**. Testing was performed by an independent test lab, accredited by the FDA and certified for compliance with **ISO/IEC 17025:2005 General Requirements for the competence of Testing and Calibration Laboratories**.


We certify that the following products are Non-Cytotoxic:

<u>Article Nos.</u>	<u>Product Family</u>
NB200-series	Non-Padded Hip Belts, 2-pt.
HB200-series	Padded Hip Belts, 2-pt.
HB400-series	Padded Hip Belts, 4-pt.
EB200-series	EvoFlex Hip Belts
PD300-series	Slip-on Pads for Belts
LH600-series	Leg Harnesses
SH120-series	Monoflex Chest Supports
SH210/220-series	H-style Harnesses
SH230/235/240-series	Trimline Harnesses
SH250/260/290-series	PivotFit Harnesses, Standard
SH270/280/290-series	PivotFit Harnesses, Dynamic
SH300-series	Stayflex Chest Supports
SP102/103-series	Calf Supports, Aeromesh
FT200-series	Ankle Huggers
PC100-series	Flex-shaft Joystick Handles

Note:

The above product families are made using identical materials and processing to those included in our tests, resulting in a score of 0, 1, or 2 per ISO 10993-5. Copies of these tests are available on request:

- *Agar Overlay Cytotoxicity Assay Solid Test Article (ISO) DIA007-CY01 Final Report (LP002 pad).pdf*
- *Agar Overlay Cytotoxicity Assay Solid Test Article (ISO) DIA008-CY01 Final Report (LP009 pad).pdf*
- *Agar Overlay Cytotoxicity Assay Solid Test Article (ISO) DIA010-CY01 Final Report (FS311 binding tape).pdf*
- *Agar Overlay Cytotoxicity Assay Solid Test Article (ISO) 942661-S01 (FS303 webbing test article D).pdf*
- *Agar Overlay Cytotoxicity Assay Solid Test Article (ISO) 970308-S01 (LP021 sheet 17-0718).pdf*
- *Agar Overlay Cytotoxicity Assay Solid Test Article (ISO) 970308-S01 (MT108 sheet 17-1213).pdf*
- *Agar Overlay Cytotoxicity Assay Solid Test Article (ISO) 970308-S01 (FS162 end strap 17-1213).pdf*
- *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*

Signed  Date April-27-2021
Matthew Kosh, President