



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, all types |

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*

Signed Matthew Kosh Date June 6, 2019

Matthew Kosh
President