



**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            |
| SH230/240-series    | Trimline Harnesses           |
| SH250/260-series    | PivotFit Harnesses, Standard |
| SH270/280-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 12/21/2017

Matthew Kosh  
President

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