

ISO 14971:2007 Risk Analysis

Company: Cascade Designs Inc.
4000 1st Ave. So.
Seattle, WA 98134
(206)505-9500

Declares that the following device:

Device: VARILITE® ZOID™ PSV™ Performance Cushion

Model numbers: 32800, 32200, 32400, 34400, 34600, 34800, 35500,
35700, 36600, 36800, 36000, 37700, 38300, 38800,
38000, 30600, 30800, 30000, 31100, 3440B

Accessories: 04702, 04711, 04712, 04715, 04719, 04720, 04721,
04722, 04725, 04726, 04727, 04728, 04729, 04730,
04731, 04741, 04781, 04785, 04786, 04787

Conforms to and was designed and developed in accordance with ANSI/AAMI/ISO 14971:2007/(R2010), *Medical devices – Application of risk management to medical devices.*

EU Representative: Cascade Designs Limited
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CE Certification: January 2, 2007

Drawn under the supervision of and approved by:



Randall Willett
Vice President, Medical Division

16 FEBRUARY 2011

Date