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®* **ProForm NX™** Seating System

Model numbers: 72411, 74411, 74611, 75511, 75711, 76611, 76811, 76011, 77711, 78611, 78811, 78011, 70611, 70811, 70011, 72412, 74412, 74612, 75512, 75712, 76612, 76812, 76012, 77712, 78612, 78812, 78012, 70612, 70812, 70012

Accessories: 01750, 01751, 01752, 01745, 01746, 01753, 01754, 01755, 01747, 01756, 01757, 01758, 01748, 01749, 01759, 01780, 01781, 01782, 01790, 01791, 01784, 01785, 01783, 01792, 01787, 01788, 01786, 01793, 01794, 01789, 01770, 01771, 01772, 01795, 01796, 01774, 01775, 01773, 01797, 01777, 01778, 01776, 01798, 01799, 01779

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.*

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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