

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: VARILTE[®] Evolution PSV[™] Seating System

Model numbers: 72415, 74415, 74615, 74816, 74016, 75515, 75715,
76415, 76615, 76815, 76015, 77715, 78615, 78815,
78015, 70615, 70815, 70015, 72815, 72015, 74815,
74015, 71115, 74435

Accessories: 05410, 05411, 05412, 05400, 05401, 05402, 05403,
05404, 05413, 05414, 05415, 05416, 05417, 05418,
05419, 05420, 05421, 05422, 05423, 05424, 05425,
05426, 05427, 05428, 05429, 05405, 05406, 05407,
05408, 05409, 05430, 05431, 05432, 05433, 05434,
05435, 05436, 05437, 05438, 05439, 05440, 05441,
05442, 05443, 05444, 05445, 05446, 05461, 05462,
05463, 05464, 05465, 05447, 05448, 05449, 05450,
05451, 05452, 05453, 05454, 05455, 05456, 05457,
05458, 05459, 05460, 04624, 04644, 04646, 04690,
04691, 04692, 04695, 04696, 04666, 04668, 04602,
04641, 04686, 04688, 04680, 04606, 04608, 04600,
04621, 04625, 04627, 04629, 05500, 05501, 05502,
05745, 05746, 05747, 05748, 05749, 05503, 05504,
05505, 05506, 05507, 05508, 05509, 05510, 05511,
05512, 05513, 05514, 05515, 05516, 05700, 05701,
05702, 05735, 05736, 05737, 05738, 05739, 05703,
05704, 05705, 05706, 05707, 05708, 05709, 05710,
05711, 05712, 05713, 05714, 05715, 05716, 05517,
05518, 05519, 05750, 05751, 05752, 05753, 05754,
05520, 05521, 05522, 05523, 05524, 05525, 05526,
05527, 05528, 05529, 05530, 05531, 05532, 05533,
05717, 05718, 05719, 05740, 05741, 05742, 05743,
05744, 05720, 05721, 05722, 05723, 05724, 05725,
05726, 05727, 05728, 05729, 05730, 05731, 05732,
05734, 04788, 04789, 05580, 05581, 05582, 05583,
05466, 05467, 05468, 05469, 05470, 05471

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