

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[®] Reflex[™] D Seating System

Model numbers: 73500112123; 73500112143; 73500114143;
73500114163; 73500114183; 73500114203;
73500115153; 73500115173; 73500116143;
73500116163; 73500116183; 73500116203;
73500117173; 73500118163; 73500118183;
73500118203; 73500120163; 73500120183;
73500120203; 73500117193; 73500119173;
73500119193

Accessories: 09000; 09001; 09002; 09003; 09004; 09005; 09006;
09007; 09008; 09009; 09010; 09011; 09012; 09013;
09014; 09015; 09016; 09017; 09018; 09019; 09020;
09021

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: November 6, 2014

Drawn under the supervision of and approved by:

Susan Cwiertnia, PT, MS

November 26, 2014

Susan Cwiertnia
Acting Director of Medical

Date