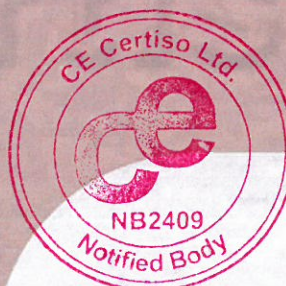


The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
unmounted bare aortic stent	AndraStent Aortic (ASA)	<p>Native and/or recurrent Coarctation of the aorta in the following patient group:</p> <p>Children, adolescent and adult patients with the following conditions:</p> <ul style="list-style-type: none"> - AndraStent Aortic XL: minimum diameter of native Aorta 8 mm - AndraStent Aortic XXL: minimum diameter of native Aorta 12 mm <p>and</p> <ul style="list-style-type: none"> - access to the treated vessel without damaging the vessels and possibility to implant a Stent which can be dilated up the size of an adult aorta <p>and the following clinical conditions:</p> <ul style="list-style-type: none"> - Stenosis of the aorta resulting in significant anatomic narrowing as determined by angiography and/or non-invasive imaging - Stenosis of the aorta where Balloon angioplasty is inadequate or contraindicated - Stenosis of the aorta resulting in hemodynamic alterations, resulting in systolic pressure gradient, systemic hypertension or altered left ventricular function - systemic hypertension with a difference in systolic blood pressure between the upper and lower limbs of 20 mmHg or higher - Stenosis diameter >20% of the adjacent vessel diameter 	<p>AndraStent Aortic XL ASAnnXL</p> <p>where nn is nominal lengths: 13, 17, 21, 26, 30, 35, 39, 43, 48, 57 mm</p> <p>extended diameter range: 8-25 mm</p> <p>AndraStent Aortic XXL ASAnnXXL</p> <p>where nn is nominal lengths: 21, 26, 30, 35, 39, 43, 48, 57 mm</p> <p>extended diameter range: 12-32 mm</p>	III

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