

## Medical Device Details

Sponsor:	Ossur New Zealand Limited 6/80 Westpoint Drive Hobsonville Auckland New Zealand
WAND Reference:	250701-WAND-75U6HM
Sponsors Own Reference:	BL Tech Cast Tape
GMDN:	Cast construction material [33056]
Class:	I
Intended Purpose:	A plastic, fiberglass, or plaster-containing substance (or other material) that is applied in layers around an injured body appendage to construct a stiff dressing (cast) in order to immobilize fractured bones, diseased joints, or painful sprains. This is a single-use device.
Manufacturer:	BL Tech Co Ltd No 857 Toegae-dong Chuncheon-si Gangwon-do South Korea
ARTG ID:	442313
	<ul style="list-style-type: none"> <li>› The device is supplied unsterilised.</li> <li>› The device is not intended to be invasive.</li> <li>› The device is intended for single use.</li> <li>› The device is not an active device.</li> <li>› The device does not contain material or ingredients of microbial origin.</li> <li>› The device does not contain material or ingredients of recombinant origin.</li> <li>› The device does not contain material or ingredients manufactured or formulated using a genetically modified organism.</li> <li>› The device does not contain material or ingredients of human origin.</li> <li>› The device does not contain human blood or its components.</li> <li>› The device consists of: Single product</li> <li>› The device does not contain material or ingredients of animal origin.</li> <li>› The device is not medicated.</li> <li>› The device is not formulated.</li> <li>› The product does not contain a medicine that has consent for marketing in New Zealand.</li> <li>› The product does not contain a medical device which incorporates a medicine as an integral part and that has an action ancillary to the device.</li> </ul>
Status:	Active