



Medical Devices Essential Principles Checklist

Manufacturers must demonstrate their medical device complies with the Essential Principles. Manufacturers must generate, collate, assess, and maintain scientific and clinical evidence that shows that their devices comply with the Essential Principles. The evidence must be relevant to the device's intended purpose and must be objective, sufficient, and robust.

- The [Essential Principles Checklist](#) is a template that may help you:
 - identify the safety and performance requirements that apply to your device
 - document a rationale for any of the safety and performance requirements that aren't relevant
 - summarise the evidence you hold in support of each of the relevant safety and performance requirements
- Completing the checklist could help you:
 - apply for an Australian conformity assessment certificate
 - comply with regulations as part of a post-market review or investigation
 - to determine if you have considered and addressed all the requirements with supporting evidence

Instructions

- Complete this checklist for each new medical device conformity assessment application
- Provide an updated checklist if applicable, for change applications relating to your medical device.
- The checklist must be applicable to the subject medical devices or may be completed for a family or group of devices.
- Complete the checklist as outlined in the table instructions below

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Table instructions

Reference to Therapeutic Goods (Medical Devices) Regulations 2002 Schedule 1, Part number and title		Applicable	Not applicable <i>Justification must be provided below</i>	Medical Devices / IVD standard or other procedure applied	Evidence of compliance <i>Include direct reference to documents within the manufacturer's quality system</i>
EP Reg.#	Title of the Essential Principle				
EP.# Reg.#	The Essential Principle requirement is contained here.	<input type="checkbox"/> Tick this box if the Essential Principle requirement is applicable to the device / family of devices. Complete the two columns on the right.	<input type="checkbox"/> Tick this box if the Essential Principle requirement is not applicable to your device / family of devices. Then provide justification.	List here the standards / procedures applied with justification (include number / title / version). These include (but are not limited to): <ul style="list-style-type: none"> • EN ISO international, local standards • company procedures • TGA Medical Device Standard Order • TGA Conformity Assessment Standard Order • TGA Guidance document 	This column is to contain direct reference to documents within the manufacturer's quality system such as: <ul style="list-style-type: none"> • study results • test reports • design outputs identified by number / title / version

Medical Devices Essential Principles Checklist

Kathleen Armour



Medical Devices Essential Principles Checklist:

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I have a 2001 Daewoo Lanos. The engine revs is too fast. It Feb 22, 2008 — The first thing to do is to disconnect the idle air control valve. This is located on the side of the throttle body (where the throttle cable ... Daewoo Lanos Idle Rev issue Apr 1, 2010 — The car is a W reg. The problem is that the revs idle at around 1k, she says that when she is driving she can hear the revs going high even ... Daewoo Lanos high Idle speed Hi,. My Daewoo Lanos is having a problem with its idle speed being too high. At a standstill it idles at about 1600rpm, and can be a bit embarassing SOLVED: My daewoo lanos 1999 wont idle at the lights it Feb 23, 2011 — Remove the idle air control motor (IAC) and clean it well and the hole it comes out of with throttle body spray cleaner, or carburetor cleaner ... Daewoo Lanos Stalls: causes and solutions Hello, I have a Lanos and its problem is that it is always powerless and tends to stall. When turning the air conditioning on, this failure is even more ... Rough Idle: Hi Again Everyone, My Lanos ... May 21, 2009 — Hi Again everyone, my lanos idles very rough, doesn't stall, seems to lack power when driving, recently replaced plugs, leads, air filter ... My 2001 Daewoo has a rough idle after. Dec 30, 2012 — It shakes and studders a lot. Sometimes the car stalls and I have to press the gas pedal in order for the car to keep running. After it warms up ... my 2001 daewoo lanos keeps dying when i come to a stop Jun 2, 2014 — I have Daewoo lanos 16v it can't start plugs firering timing is good i spray qikstart meas start fluid nothing happen it doesn't have camshaft ... Daewoo Matiz Idle Woes - YouTube Daewoo Lanos Idle Air Control Valve Order Daewoo Lanos Idle Air Control Valve online today. Free Same Day Store Pickup. Check out free battery charging and engine diagnostic testing while you ... Free Arkansas Quit Claim Deed Form - PDF | Word An Arkansas quitclaim deed is a form that is used to transfer property from a seller to a purchaser without any warranty on the title. This type of deed only ... Quitclaim deeds This deed must be signed, notarized, and recorded in the county where the property is located. Some counties have more than one recording

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