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2021 3 5 a medical device can be any instrument apparatus implement machine appliance implant reagent for in vitro use software material or other similar or related article intended by the manufacturer to be used alone or in

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medical device an instrument tool machine test kit or implant that is used to prevent diagnose or treat disease or other conditions medical devices range from tongue depressors to heart pacemakers and medical imaging equipment

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classification of medical devices in japan medical devices are classified into four classes based on the risk level class i extremely low risk class ii low risk class iii medium risk and class iv high risk

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