



Faculty of Engineering
Department of Biomedical Engineering

02

Medical Device Classification

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BME 312

Biomedical Instrumentation II

What is a Medical Device



Medical Device



A medical device is any device intended to be used for medical purposes.

“the intended use” is important.



- The intended use is important.
- Tongue Depressor
 - A wooden stick

Medical Device

A medical device is any device intended to be used for medical purposes.

Medical Care

- Diagnosis,
- Therapy,
- And monitoring.

Diagnostic devices



- Types of diagnostic devices
 - recording and monitoring devices
 - measurement and analysis devices
 - imaging devices

Assistive or rehabilitative devices

How to Categorize Medical Devices



- Informal – Group of Medical Devices
 - In terms of medical care.

Diagnosis

Therapy

Monitoring

Rehabilitation

European Union Medical Device Directive



european union medical device directive