

CLASSIFICAZIONE

Sistema K-PLATE

REFERENCES

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007
MEDICAL DEVICES: Guidance document - Classification of medical devices (MEDDEV 2.4/1 Rev.9)

Sistema "K-Plate" - Viti e placche

Rule		A	NA
Rule 1	Non-invasive devices that either do not touch the patient or contact intact skin only	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Rule 2	Non-invasive devices channelling or storing for eventual administration	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Rule 3	Non-invasive devices that modify biological or chemical composition of blood, body liquids or other liquids intended for infusion into the body	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Rule 4	Non-invasive devices which come into contact with injured skin	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Rule 5	Devices invasive with respect to body orifices	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Rule 6	Surgically invasive devices intended for transient use (< 60 minutes)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Rule 7	Surgically invasive devices intended for short-term use (>60 minutes, <30 days)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Rule 8	Implantable devices and long-term surgically invasive devices (> 30 days)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Rule 9	Active therapeutic devices intended to administer or exchange energy	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Rule 10	Active devices for diagnosis	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Rule 11	Active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Rule 12	All other active devices	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Rules 13-18	Special Rules	<input type="checkbox"/>	<input checked="" type="checkbox"/>

APPLICATION

Upper and lower limbs

CLASSIFICATION

Implantable devices (surgically invasive) intended for long-term use

Class I non sterile	Class I sterile	Class IIa	Class IIb	Class III
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Sistema "K-Plate" - Kirschner Wires e Kit

Rule		A	NA
Rule 1	Non-invasive devices that either do not touch the patient or contact intact skin only	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Rule 2	Non-invasive devices channelling or storing for eventual administration	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Rule 3	Non-invasive devices that modify biological or chemical composition of blood, body liquids or other liquids intended for infusion into the body	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Rule 4	Non-invasive devices which come into contact with injured skin	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Rule 5	Devices invasive with respect to body orifices	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Rule 6	Surgically invasive devices intended for transient use (< 60 minutes)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Rule 7	Surgically invasive devices intended for short-term use (>60 minutes, <30 days)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Rule 8	Implantable devices and long-term surgically invasive devices (> 30 days)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Rule 9	Active therapeutic devices intended to administer or exchange energy	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Rule 10	Active devices for diagnosis	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Rule 11	Active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Rule 12	All other active devices	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Rules 13-18	Special Rules	<input type="checkbox"/>	<input checked="" type="checkbox"/>

APPLICATION

Upper and lower limbs

CLASSIFICATION

Kirschner Wires (surgically invasive for transient use)

Instrumentation kit (class I instruments and a drill bit to be connected to an active devices) has been classified taking into consideration classification of the higher class device included in the kit.

Class I non sterile	Class I sterile	Class IIa	Class IIb	Class III
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Sistema “K-Plate” – Single instruments (except drill bits)

Rule		A	NA
Rule 1	Non-invasive devices that either do not touch the patient or contact intact skin only	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Rule 2	Non-invasive devices channelling or storing for eventual administration	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Rule 3	Non-invasive devices that modify biological or chemical composition of blood, body liquids or other liquids intended for infusion into the body	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Rule 4	Non-invasive devices which come into contact with injured skin	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Rule 5	Devices invasive with respect to body orifices	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Rule 6	Surgically invasive devices intended for transient use (< 60 minutes)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Rule 7	Surgically invasive devices intended for short-term use (>60 minutes, <30 days)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Rule 8	Implantable devices and long-term surgically invasive devices (> 30 days)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Rule 9	Active therapeutic devices intended to administer or exchange energy	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Rule 10	Active devices for diagnosis	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Rule 11	Active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Rule 12	All other active devices	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Rules 13-18	Special Rules	<input type="checkbox"/>	<input checked="" type="checkbox"/>

APPLICATION

Upper and lower limbs

CLASSIFICATION

Non invasive instruments and surgically invasive reusable instruments.

Class I non sterile	Class I sterile	Class IIa	Class IIb	Class III
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>