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Data sheet

qmd® ultrasound cryo thermal and qmd® cryo thermal PT

Technical specifications

mains voltage	100-240 V, 220 V - 50 Hz/60 Hz
power absorption	max. 180 W
full colour LCD touch screen 10.1"	
working mode	only ultrasound, only cryo-thermal, or combined ultrasound cryo-thermal
ultrasound frequency range	1 MHz and 3 MHz (± 5%)
ultrasound output power	from 0.2 W/ cm^2 to max. 3 W/cm^2 (± 20%)
ultrasound mode	fixed, pulsed and thynk 1 and thynk 2 (continuous alternating from 1 to 3 MHz)
pulse range	from 20 Hz to 100 Hz, in step of 10 Hz
efficiency radiation area (ERA)	2.3 cm^2 ±20%
temperature tolerance	± 3 °C
thermal range	+30 °C to +42 °C
cryo range	-2 °C to +15 °C
cryo-thermal mode	fixed, contrast therapy (alternating cycles), thermal shock (fast drop from +34 °C to +4 °C)
security class	1 type BF
ambient temperature	18 °C ÷ +30 °C
storage and transport temperature	-40 °C ÷ +85 °C
relative humidity	35-80 %, non-condensing
dimension	340 x 220 x 217 mm
weight	7.5 kg

Medical Devices Directive

The devices **qmd® ultrasound cryo thermal** and **qmd® cryo thermal PT** are in compliance with the standard 93/42/EEC and marked with the number “CE 0068”.

European Directives ROHS

The devices **qmd® ultrasound cryo thermal** and **qmd® cryo thermal PT** are made in compliance with the standard ROHS. The devices **qmd® ultrasound cryo thermal** and **qmd® cryo thermal PT** are made of recyclable materials.

The devices **qmd® ultrasound cryo thermal** and **qmd® cryo thermal PT** are therapeutic devices classified according to rule 9 of Annex IX of Directive 93/42 EEC and subsequent amendments as:

- medical devices of class IIb.

Furthermore, the devices **qmd® ultrasound cryo thermal** and **qmd® cryo thermal PT**:

- they are active medical devices;
- they are devices with non-invasive application;
- not suitable for sterile use;
- they aren't single-use devices;
- they aren't measuring devices;
- they aren't "to measure" devices;
- they do not contain phthalates.

According to the general rule EN60601-1 current version for the safety are applied the following classifications:

- class I equipment;
- equipment with applied part of type BF;
- ordinary equipment (with a case that does not protect against water penetration).

The medical devices **qmd® ultrasound cryo thermal** and **qmd® cryo thermal PT** are manufactured in accordance with the standards:

- UNI CEI EN ISO 14971:2020
- CEI EN 60601-1:2014
- CEI EN 60601-1-1: 2003
- CEI EN 60601-1-2: 2018
- CEI EN 60601-1-6: 2011
- CEI EN 60601-1-8: 2020
- CEI EN 60601-2-5: 2016
- CEI EN 61689:2009
- CEI EN 62353:2017
- CEI UNI EN 980:2010
- CEI UNI EN 1041:2013
- 93/42/CEE
- 2004/108/EEC
- CEI EN 62304:2016
- UNI CEI EN ISO 15223-1:2018
- UNI EN ISO 10993-1:2018
- IEC 62366-1:2016