

Vallauris, le 05 mars 2013,

I, Guillaume TOURREL, R & D manager, certify that the medical device DIGISONIC SP is consistent with the requirement of the standard for cochlear implants EN 45502-2-3: 2010, § 22.1 concerning the compatibility with the diagnostics by ultrasounds .

The implant may be subjected to an ultrasonic energy of 500 W / m² for one hour in a time mode means, for frequencies between 2 MHz and 5 MHz.

Recommendation:

Whenever possible, avoid diagnostics by ultrasounds in direct contact with the implant. In any other part of the body, the use of ultrasound for diagnostic purposes is contraindicated.

The ultrasounds require for therapeutic and energy purposes that exceed the level defined above should not be applied directly to the implant or in the settlement area of the implant. The practitioner will ensure, in all cases, that the scope of the ultrasound will not reach the area of the implant.

Guillaume TOURREL

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