

23.11.2017

To whom it may concern,

Medi-Direct International Ltd is the owner and manufacturer of the Medical Devices *Paingone* and *Paingone Plus*.

Both devices bear the CE mark and are compliant with the Medical Devices Directive (93/42/EEC). Medi-Direct International Ltd also holds certifications to ISO standard 13485 for Medical Devices.

Both products may therefore be freely placed on the European market without limitation.

Paingone and *Paingone Plus* and their labelling have been registered with the *Agence Nationale de Sécurité du Médicament et des Produits de Santé* in France. They may be marketed using the medical claims previously reviewed and approved by the *ANSM*.

We confirm that the information above is true and accurate.

Jason Timms
Managing Director

The logo for Medi-Direct International, featuring the company name in a sans-serif font with a small blue cross icon to the right of the word 'direct'.

medi direct⁺
i n t e r n a t i o n a l

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