




December 1, 2009

This statement is in response to an update in the Medical Device Directive, the rules for the governance of the CE Mark. Effective date of the new compliance regulations is 21 March 2010.

For products listed below and bearing the  symbol, the following statement applies "For Infection Control Purposes, this device is recommended for patient-dedicated use. The ability to effectively clean this single use device has not been established and subsequent re-use may adversely affect the performance and/or safety of the device."

These products are covered by this statement:

Klear-Trace® Electrodes (all types and sizes)
NeoGuard® Temperature Probes (all types and sizes)
NeoGuard Thermal Reflectors (all types and sizes)
NeoGuard Limboard® Arm Boards (all types and sizes)

Elizabeth Schmidt
Product Manager
Mother/baby products

