TATA SURGICAL (PVT) LTD

Directive 93/42/EEC

on medical devices, Annex V

Issue 2

Detailed scope

Sterile & Non-Sterile, Single Use, General Surgery Scissors, Sterile & Non-Sterile Single Use, General Surgery Dissecting & Tissue Forceps Sterile & Non-Sterile Single Use General Surgery Hemostatic Forceps, Sterile & Non-Sterile Single Use General Surgery Needle Holders Sterile & Non-Sterile Single Use General Surgery Retractors, Sterile & Non-Sterile Single. Use General Surgery Suction Tubes, sterile & non sterile surgical cannulas, sterile & non sterile surgical probes, sterile & non sterile single use ophthalmic forceps, sterile & non sterile single use ophthalmic calipers, sterile & non sterile single use ophthalmic hooks, sterile & non sterile single use ophthalmic needle holders, sterile & non sterile single use ophthalmic scissors, sterile & non sterile single use surgical curettes, sterile & non sterile single use Redon Needles, sterile & non sterile single use Scalpel Blade Handles.

Annex V Sterility aspects only. Restricted to the aspects of manufacture concerned with securing & maintaining sterile conditions;

Sterile single use nasal speculum, sterile single use vaginal speculum & sterile single use ophthalmic speculum.

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market

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