

Recommendation:-

The MDAC (Miscellaneous) deliberated the proposals on 04.10.2013 and recommended the following:-

Agenda No.	File No.	Name of the Firm & Name of the Proposed product	Recommendations
1.	4-MD/CT-98/2013-DC	M/s Baxter India, Gurgaon has applied for the registration of Peri-strips Dry with Veritas® collagen Matrix (PSDV) in two configurations PSDV-Linear & PSDV- Circular along with PSD gel as a bonding agent.	The committee reviewed the proposal and found that proposed device is not a ne device because the device material Bovine Pericardium is already been used in Indian population. The clinical trial data submitted by the firm was found adequate. The committee after deliberation recommended that the proposal may be considered for grant of registration for marketing the said device with the condition that the firm should Phase-IV clinical trial in statistically significant population geographically distributed across the country