

DECISION SHEET

Standard(s)- (year and edition): IEC 60601-1:1988 Ed.2 Am1+Am2	Sub clause(s): 20.1	Sheet n°: DSH-411
Subject: General requirements	Key words: Leakage current, SIP/SOP, working voltage, A-k	Confirmed by CTL at its 39th meeting, in Cologne
<p>Question:</p> <p>i) Does exemption a) refer to voltages arising within the EQUIPMENT, to voltages appearing from external sources, or both?</p> <p>ii) Does exemption b) refer to the SFC of mains voltage on the SIP or SOP? Is insulation which ensures absence of excessive LEAKAGE CURRENTS not to be tested?</p> <p>iii) For exemption d) to apply, does the manufacturer have to restrict connection of the SIP and SOP to other MEDICAL ELECTRICAL EQUIPMENT or can connection to non-medical equipment be permitted, subject to some restrictions?</p> <p>Decision:</p> <p>i) a) applies only if the voltages within the SIP and SOP are less than SELV when connected to EQUIPMENT consistent with the instructions for use.</p> <p>ii) b) applies to a SFC resulting from a single component failure within the SIP or SOP in NORMAL USE i.e. connected as specified in the instructions for use. If such a SFC does not produce excessive LEAKAGE CURRENTS then no additional insulation test is needed.</p> <p>iii) d) applies only if the manufacturer restricts connection of the SIP or SOP to MEDICAL ELECTRICAL EQUIPMENT</p> <p>Explanatory notes:</p> <p>a) is intended to cover the working voltages on the SIP or SOP in NORMAL USE regardless of their origin.</p> <p>b) is intended to cover the SFC caused by a component failure within the SIP or SOP in NORMAL USE.</p> <p>d) exemption does not allow connection to equipment, only Medical Electrical EQUIPMENT, as defined is covered.</p>		