

April 3rd, 2013

To Whom It May Concern,

Items that are used in the healthcare environment, but which are not classified as medical devices under the Medical Devices Directive, should not be CE marked. Examples of such devices are biological and chemical indicators used in sterilization processes as, to the best of our knowledge, these products are not considered medical devices and not manufactured according to directives 93/42 EEC and 98/79 EC. A partial listing of SPSmedical products that fall under this category are listed below. Even though these items are not CE marked, SPSmedical manufactures these products to meet the performance requirements of their applicable ISO standard (in most cases either ISO 11138 or ISO 11140).

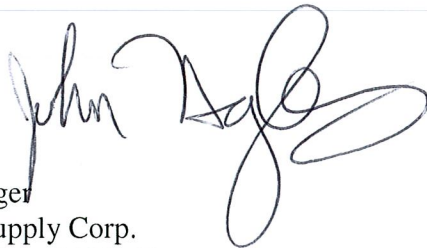
Cat. No.	Description
SSI-100	STEAMPlus Steam Sterilization Integrator
SSI-1000	STEAMPlus Steam Sterilization Integrator
TRC-050	STEAMPlus Tray Record Card
STP-025	STEAMPlus Sterilizer Test Pack
PRC-250	DUAL Patient Record Card
UPC-250	UNIVERSAL Patient Record card
SIT-100	Steam Indicator Tube
SIS-250	Steam Indicator Strip - Short
SIL-250	Steam Indicator Strip
SIL-250-L	Steam Indicator Strip - Laminated
SIP-001	Steam Indicator Pen
DIS-100	Dry Heat Indicator Strips
VIS-100	Chemical Vapor Indicator Strip
SFS-250	Formaldehyde Indicator Strip
GIL-250	EO gas Indicator Strip
GSM-100	EO gas Sterilizer Monitor
DMS-250	DUAL Monitor Strip
DMS-250-L	DUAL Monitor Strip - Laminated
GPS-250R	Gas Plasma Chemical Indicator Strip - 4"
PAS-050	Peracetic Acid Chemical Indicator Strip
DIL-1000	Dry Heat Indicator Label
RIL-1000	Radiation Indicator Label
SGL-1000	DUAL Indicator Label
GIL-1000	EO gas Indicator Label
SIL-1000	Steam Indicator Label
GPL-2000R	Gas Plasma Indicator Label
STL-250	Steam Tag Indicator Label
DTL-125	Dry Heat Tag Indicator Label
SBD-030	AirView Disposable B-D test pack
BDS-050	Bowie-Dick Test sheets
LCR-025	Lantor Cube reusable B-D test pack
LCP-001	Metal Clamp for use w/Lantor Cube

SA-100	SporAmpule Steam BI
SBT-025	SporView Steam BI Test Pack w/ 25 controls
SBT-255	SporView Steam BI Test Pack w/ 5 controls
SCP-025	SporViewPlus Self-Contained Steam Biological Indicator
SCP-050	SporViewPlus Self-Contained Steam Biological Indicator
SCS-025	SporView Self-Contained Steam BI
SCS-100	SporView Self-Contained Steam BI
SCG-025	SporView Self-Contained EO gas BI
SCG-100	SporView Self-Contained EO gas BI
PCS-025	SporView PA Culture Set
CS-020	SporView Culture Set
CS-100	SporView Culture Set
DS-100	SporView Dual Species Strip
DS-1000	SporView Dual Species Strip
BS-105	SporView B. stearo 10 ⁵ strip, 100/bg
BS-106	SporView B. stearo 10 ⁶ strip, 100/bg
BS-505	SporView B. stearo 10 ⁵ strip, 500/bg
BS-506	SporView B. stearo 10 ⁶ strip, 500/bg
BG-106	SporView B.atrophaeus 10 ⁶ spore strip, 100/pk
BG-107	SporView B.atrophaeus 10 ⁷ spore strip, 100/pk
BG-506	SporView B.atrophaeus 10 ⁶ spore strip, 500/pk
BSV-106	SporView B. stearo. 10 ⁶ spore suspension, 10 ml
BSV-107	SporView B. stearo. 10 ⁷ spore suspension, 10 ml
BSV-108	SporView B. stearo. 10 ⁸ spore suspension, 10 ml
BGV-106	SporView B.atrophaeus 10 ⁶ spore suspension, 10 ml
BGV-107	SporView B.atrophaeus 10 ⁷ spore suspension, 10 ml
ST-072	Steam Indicator Tape
ST-048	Steam Indicator Tape
ST-036	Steam Indicator Tape
BT-048	Blue Steam Indicator Tape
BT-036	Blue Steam Indicator Tape
GT-048	EO Gas Indicator Tape
GT-036	EO Gas Indicator Tape
HT-048	VH202 Indicator Tape
VT-048	Chemical Vapor Indicator Tape

If there are any questions or concerns, please feel free to contact me directly.

Sincerely,

John Hughes



John Hughes
 General Manager
 SPSmedical Supply Corp.
 FDA Registration: 1319130



Cc: file