

## Certificate of Conformity

We, SP Medikal San Ltd Sti., represented by undersigned, herewith declare that the

Sterintech™ 2 Line label gun indicator labels and 3 Line label gun indicator labels (with ref. nr. 602.xxx.9000, 603.xxx.9000, 604.xxx.9000 and 605.xxx.9000) and their raw materials have been selected to fulfill the general requirements of various sterilization applications and in case of steam sterilization application have been tested in a CIER-Vessel based upon the requirements as per ISO 11140 part 1.

We herewith confirm that the Sterintech™ 2 Line and 3 Line label gun indicator labels are designed and compliant to the following standard:

Chemical Indicator: **ISO 11140-1, 2005:**  
**'Sterilization of health care products**  
**Chemical indicators -- Part 1: 'General requirements'**

Based upon tests as per the above-mentioned standard chemical indicator is classified as class 1

The label material and indicator ink comply to REACH guidelines. Any of the raw materials we use do not contain Natural Rubber Latex and are non-toxic as well as heavy metal free.

Indicators exposed to sterilization conditions and have reached their end-color can be kept for record for a period of 10 years when stored under the storage conditions as displayed on our box label / carton.

Label gun labels are not listed as Medical Device.

21st Mai 2012

Seda Küçükylmaz  
Quality Department

Peter M. den Uil (B. Sc.)  
Managing Partner