



ONAYLANMIŞ KURULUŞ 2195 ®

SZUTEST

CE
2195

EC CERTIFICATE

According to Annex V of the Directive 93/42/EEC on Medical Devices

Production Quality Assurance System

Certificate Number: 2195-MED-1323301

Manufacturer: Sentech Korea Co., Ltd.
21-6, Jimokro 75-gil, Paju-si, Gyeonggi-do 413-170, Republic of Korea

Product(s): BREATHALYZER (Breath Alcohol Tester)

Type(s)/Model(s): ALCOSCAN ALP-1

Final Report No: 2195-MED-1308003

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex V, Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product category(ies) and accessories and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex V, Section 4 of Directive 93/42/EEC.

Szutest must be informed of any significant changes in the design and/or construction of the product category(ies).

This EC certificate is valid till 2018.08.20

Istanbul, 2013.08.21



Mehmet IŞIKLAR
General Manager

