

DICHIARAZIONE NON DISPOSITIVO MEDICO

DECLARATION NOT MEDICAL DEVICE

I seguenti prodotti non sono classificati come dispositivi medici, pertanto non è richiesta la Dichiarazione di Conformità ai sensi del Regolamento (UE) 2017/745.

Following products are not classified as medical devices, therefore Declaration of Conformity as per Regulation (EU) 2017/745 is not required.

Description	SP International Code	Gima Code	Intended use
BOWIE DICK TEST PACK	102.002.0020	35950	Checking Steam steriliser performance
BOWIE DICK HELIX TEST PACK	101.201.0100	35951	Checking Steam steriliser performance
CLASS 5 MOVING FRONT INTEGRATOR	105.003.1000	35952	Checking Steam cycle parameters
CLASS 5 STEAM INTEGRATOR	105.103.0500	35953	Checking Steam cycle parameters
SEAL CHECKER	909.001.0250	35957	Checking the sealing machine performance
PLASTIC SECURITY SEAL - blue	902.111.1000	37330	Prevention of opening sterile containers
PLASTIC SECURITY SEAL WITH STEAM INDICATOR - blue	902.112.1000	37332	Prevention of opening sterile containers
CONTAINER CARD WITH STEAM INDICATOR	903.101.0250	37333	Process indicator to indicate sterilised or not
SELF-ADHESIVE CONTAINER SEAL LABEL WITH PIN	902.105.1100	37334	Prevention of opening sterile containers
PLASTIC SECURITY SEAL - red	902.113.1000	37340	Prevention of opening sterile containers
PLASTIC SECURITY SEAL - yellow	902.115.1000	37341	Prevention of opening sterile containers
PLASTIC SECURITY SEAL WITH STEAM INDICATOR - red	902.114.1000	37343	Prevention of opening sterile containers
PLASTIC SECURITY SEAL WITH STEAM INDICATOR - yellow	902.116.1000	37344	Prevention of opening sterile containers

Infatti, la destinazione d'uso del prodotto non è compatibile con la definizione di dispositivo medico.

In fact, the intended use of the product doesn't match with the definition of medical device.

Nome del Fabbricante/ <i>Manufacturer name</i>	Indirizzo postale ed elettronico a cui il fabbricante può essere contattato / <i>postal and electronic address at which manufacturer can be contacted</i>
SP Medikal San Ltd Sti	Yenidoğan Mahallesi, Erciyes Sokak No:16/2 , 34035 Bayrampaşa , İstanbul , Türkiye Email: info@spmedikal.com

Dichiarazione sotto piena nostra responsabilità -
Declaration under our own responsibility

Istanbul 26/01/2026

SP Medikal San Ltd Sti

Seda Küçükyılmaz
Gestione della Qualità

SP Medikal San Ltd Sti

Peter M. den Uil (B. Sc.)
Socio Dirigente