

Declaration of Conformity

Manufacturer: SP Medikal San Ltd Sti.,

Products: Sterintech™ Container Filters with Reference numbers:

- 901.101.1000 with indicator in centre Diameter: 19 cm
 901.102.1000 with indicator on lash Diameter: 19 cm

Classification: The above listed Medical Devices are classified in accordance with Rule 1 of Annex VIII as **Class 1 non-sterile, non-measuring devices**

We herewith declare that this declaration of conformity is issued under the sole responsibility of SP Medikal San Ltd Sti and that the above mentioned products meet the provisions of Regulation Eu 2017/745 for Medical Devices (MDR)

All products have been subjected to conformity assessment procedure according to the EU MDR.

All supporting documentation is retained on the premises of the SP Medikal San Ltd Sti.

The above listed products are produced under the ISO 13485 quality assurance system in place.

Start of CE-marking : 2011-06-01
SRN: -
Basic UDI-DI: 8680869116955 - 901.101.1000
8680869115408 - 901.102.1000

Place, Date of Issue: SP Medikal San Ltd Sti , Deliklikaya Mah. Cubuklu Cad. No. 39
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