EU Declaration of Conformity

Manufacturer: SP Medikal San Ltd Sti.,

Products: Sterintech™ Container Filters with Reference numbers:

- ☑ 901.001.0100 Container Filter with indicator in centre Diameter: 19 cm
- ☑ 901.001.0500 Container Filter with indicator in centre Diameter: 19 cm
- ☑ 901.002.0500 Container Filter 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**

Intended use: The filters are used to prohibit contaminations to enter the container in order to keep the surgical instrument sterile.

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:	TR-MF-000027264
Basic UDI-DI:	8680869116955 - 901.001.0500 8680869115408 - 901.002.0500
GMDN:	13735
EMDN:	S010301

Place, Date of Issue: SP Medikal San Ltd Sti , Deliklikaya Mah. Cubuklu Cad. No. 39 Arnavutkoy 34555 - Istanbul - Tur

2 January 2025

Seda Kücükyilmaz
Quality Management

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