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THE SYRINGE FILLING PLANT
(Prefilled Syringe)

Mefar Kurtkoy Site
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Attachment –1 Technical drawing of 10 ml nest
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1- Introduction

By installing the Prefilled Syringes Process at Mefar Kurtköy Facilities, we will be able to perform the filling, optical control, labelling, blistering, and packaging procedures of syringes with or without needles. We will also be able to produce and work with cold chain products, thanks to our cold room storage.

2- Function of Filling Machine

The empty syringes that arrive in sterile conditions will be filled and fitted with a stopper under aseptic sterile conditions in a fully automated manner.

3 – Specification of the Filling Machine:

Model no : DFVN 2000
Serial no : 6805
Production year : 2007
Manufacturer : Groninger
Operating volumes : 1,00 ml – 50,00 ml
Theoretical capacity : Varies according to volume. Average capacity:

\[
10 \text{ ml} \rightarrow \sim 36 \text{ unit/minute} \rightarrow \sim 2.200 \text{ unit/hour}
\]

4 – Definition of Equipments used

a - Tub : Container for empty/filled syringes inside the nest
b - **Tyvek**: Protective paper on tub.

c - **Nest**: *Perforated plate that ensures that the empty/filled syringes are stacked in an orderly manner.*

d - **Ready to fill syringe**: Empty and sterile syringe ready for the filling

e - **Stopper**: Bromobutyl Stoppers can be obtained presterilised or can be sterilised just before use.
5 – **Filling process diagram**

* a- The nylon bag containing the tub (item 3-a) and pushing the tub onto the conveyor belt going into the sterile section.

![Image 1]

b – *Removal of the tyvek (item 3-b)* on the tub.

![Image 2]

c - *Installation of the nest (item 3-c)* carrying the empty syringes within the tub, into the filling station by the robot lever

![Image 3]

d – *Placing the empty tub on the exit of conveyor via the robot lever.*

![Image 4]
e – Automated filling at the filling station and the fastening of the sterile stoppers (fumigation during filling process)

f – Placing of empty syringes and nest into the empty tub on the exit conveyor by the robot lever.

g – Automated exit of filled syringes by means of the conveyor.
6 – General procedures

a – The empty syringes to be used, are taken into C-class via airlock from D-class after unpacking and desinfection.

b – The nylon package covering the tub containing the empty syringes in C class, is removed and the tub is placed onto the feeding conveyor of the machine in B class.

c – The tyvek is opened at the entrance of the machine under laminar flow (A class) with the help of gloves and plyers.

d – The empty syringes in the tub on the conveyor belt are placed into the filling center station by the robot lever.

e – The sterile stoppers are loaded onto the machine, the prepared sterile solution is connected to the machine via the caldron.

f – After automatically being filled and fitted with stoppers in A class, the filled syringes are taken into C class from the exit conveyor with the robot lever.

g – Depending on the specifications of the solution and the procedure, the filled syringes can be terminal sterilised in the autoclave.

h – Optical control and labelling procedures are performed.

i – According to customer’s requirements, blister packageing and covering with foil paper can be performed.

j – After packaging procedures, the product is ready for shipment.