flosteril

EU DECLARATION OF CONFORMITY

This Declaration of Conformity, issued under the sole responsibility of the manufacturer **Flomak Tekstil Makine Muh. Mum. Taah. San. Ve Tic. Ltd. Sti., Beysan Sanayi Sitesi, Birlik Caddesi No: 24 Haramidere Beylikdüzü Istanbul 34524 Turkey** hereby declaring the following Medical Device.

Product Description: : Flosteril Fluid-Protection Procedure Mask, Type IIR
Model: 2100

is/are in conformity with the provisions of the following European Regulation and national regulation.

European Union Regulations:

Medical Device Directive

Risk class of the device in accordance with Annex IX: Class 1, Rule 1

The model is/are in conformity with the provisions of Directive (EU) 93/42/EEC and 2007/47/EC including including fulfilment of the applicable essential requirements set out in Annex I, and with the National Standard transposing the harmonized European Standard Number(s):

EN 14683:2019+AC:2019
ISO 13485:2016
ISO 14971:2019
ISO 15223-1:2019

Conformity assessment procedure: N/A (self declaration)

Signed by: Zeynep Derya BİLGİN
Regulatory Affairs Executive

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