flosteril®

EU DECLARATION OF CONFORMITY

This Declaration of Conformity, issued under the sole responsibility of the manufacturer ***Flomak Tekstil Makine Muh. Mum. Taah. San. Tic. Ltd. Sti., Beysan Sanayi Sitesi, Dereboyu Caddesi No: 26 Kat: 3 Beylikduzu 35524 Istanbul, Turkey*** hereby declaring the following Product.

Product Description: Single-use Isolation Gown AAMI Level 1
Model: FLOMED-8080
EU Representative: N/A
GMDN Code(s): 35492

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 Regulation (EU) 93/42/EEC and 2007/47/EC including fulfilment of the applicable essential requirements set out in Annex I, and with the Standard transposing the harmonised European Standard Number(s):

TS ISO 13485:2016
ANSI/AAMI PB70:2012
EN ISO 14971:2019
EN ISO 15223-1:2016

Conformity assessment procedure: N/A (self declaration)

Personal Protective Equipment Regulation

Risk categories of PPE: Cat I
Risk: Protection against minimal risk – prolonged contact with water.

The model is/are in conformity with the provisions of Regulation (EU) 2016/425 including fulfilment of the applicable essential health and safety requirements set out in Annex II.

Conformity assessment procedure: Modul A set out in Annex IV of Regulation

Signed by: Ferhat Sönmez
Quality Assurance and Regulatory Affairs Manager

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