



EU DECLARATION OF CONFORMITY

This Declaration of Conformity, issued under the sole responsibility of the manufacturer **Dentapharma İlaç Medikal San ve Tic Ltd. Şti. , Kalaba Mah. Ahmet Vefik Paşa Cad. No:13/b Keçiören Ankara/TURKEY** hereby declaring the following product.

Product Description: Shoe cover

Model: TGA-HC002

EU Representative: N/A

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 including fulfilment of the applicable essential requirements set out in Annex 1, and with the Standard transposing the harmonised European Standard Number(s):

ISO 9001:2015

ISO 13485:2016

EN 13795-1:2019

Conformity assessment procedure: N/A (self declaration)

Personal Protective Equipment Regulation

Risk: Protection against moderate risk - prolonged contact with water that could occur in the medical environment.

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 Serkan DADAKOĞLU

CEO of Dentapharma Medical Co.

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