



DILAMED

Tıbbi Ürünler A.Ş.

DECLARATION OF CONFORMITY

Manufacturer:

DİLAMED TİBBİ ÜRÜNLER SAN. VE TİC. AŞ.

Yazılıbaşı Mah. Fatma Tonkuş Cad. No:24 TORBALı / İZMİR

Phone: 0232 281 11 25

Product(s)

Iodine

DLM0009-1 Single Use Surgical Hand Brush Impregnated with 7.5% Povidone

DLM0010-1 Single Use Surgical Hand Brush Impregnated with 4%

Chlorhexidine Gluconate

Classification

Biocidal Product (Not a Medical Device)

According to your report dated 12.02.2015 and the document titled "Manual On Borderline And Classification In The Community Regulatory Framework For Medical Devices Version 1.16", it has been stated that hand and nail brushes cannot be considered within the scope of Medical Devices.

https://health.ec.europa.eu/system/files/2020-08/md_borderline_manual_05_2019_en_0.pdf (Pg. 51, Section 5.4)

Concomitantly, according to REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, products containing CHG 4% & PVP 7.5% are not considered pharmaceuticals, but rather are considered and designated as Biocidal products and fall under REACH guidelines for Biocidal products, regulation BPR 528/2012.

<https://echa.europa.eu/regulations/reach/legislation>

Appearance Single Use Surgical Hand Brush

Shelf Life 2 years

Competent Authority Ministry of Health of the Republic of Turkey

Dilamed Tıbbi Ürünler San. ve Tic. A.Ş.

Place, Date of Issue Izmir/Turkey –14.02.2024

Yazılıbaşı Mah. Fatma Tonkuş Cad. No: 24 Torbalı-İZMİR

Signature General Manager

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