

DECLARATION OF CONFORMITY

Manufacturer:

DİLAMED TIBBİ ÜRÜNLER SAN. VE TİC. AŞ.

Yazıbaşı Mah. Fatma Tonkuş Cad. No:24 TORBALI / 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
of Turkey

Ministry of Health of the Republic

Place, Date of Issue

Izmir/Turkey –14.02.2024

Signature

General Manager

Murat Doğu

DİLAMED TIBBİ ÜRÜNLERİ SAN.VE TİC.A.Ş.
Yazıbaşı Mh. Fatma Tonkuş Cad. No:24 Torbalı -İZMİR
Tel : 0 232 281 11 25
info@dilamedtibbi.com
Mersis No: 0298078553300001
Hasan Tahsin V.D. : 2960 716533

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

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

+90 530 681 20 38

+90 232 281 11 25

info@dilamedtibbi.com

www.dilamedtibbi.com