

EC DECLARATION OF CONFORMITY

Manufacturer's Name: Medoffice Sağlık Endüstri Anonim Şirketi

Manufacturer's Address: Yazıbaşı Mah. Kuşçu Cad. No:9/1 Yazıbaşı, Torbalı İzmir Turkey

SRN (Single Registration Number): 8681020477618, 8681020477045, 8681020477953, 8681020477458, 8681020477472, 8681020477632, 8681020477809, 8681020477816, 8683148050032

Name of the Devices: Med-Cover Barrier Cream Cloths, Med-Cover Barrier Cream Perineal Wipes, Med-Cover Wash Gloves with Barrier Cream, Med-Cover Adjustable First Aid Pediatric Cervical Collar, Med-Cover Adjustable First Aid Adult Cervical Collar, Med-Cover Lemon Glycerin Swab Sticks, Med-Cover Barrier Cream(with Zinc Oxide) 100 gr Tube, Med-Cover Barrier Cream Transparent 120 gr Tube, Med-Cover Barrier Film Spray 30 ml

Product(s) code(s): MCV0012, MCP0025, MCK0010, MCS0, MCI0, MCAB0010, MCB0010, MCB0020, MCS0010
Basic UDI-DI: 8681020477618, 8681020477045, 8681020477953, 8681020477458, 8681020477472, 8681020477632, 8681020477809, 8681020477816, 8683148050032

Classification: Class I

Conformity assessment route: company uses the following procedures for the CE-labeling of their products according to the Regulation MDR 2017/745

This declaration of conformity is issued under the sole responsibility of manufacturer. We hereby declare that the medical devices specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. The devices covered by this declaration comply with the list of supervised harmonized standards specified in the technical documentation of the devices. All supporting documentation is retained at the premises of the manufacturer.



City, date: Izmir, 26.07.2021

Appendix no. 1

List of models for the products:

Signature: Yücel TEKER, General Manager


MEDOFFICE SAĞLIK ENDÜSTRİ ANONİM ŞİRKETİ
Yazıbaşı Mah. Kuşçu Cd. No:9/1 Yazıbaşı No:1 Torbalı/İZMİR
Tel: 0 (232) 431 31 18 • Fax: 0 (232) 431 31 09
www.medoffice.com.tr • info@medoffice.com.tr
Torbalı V. D. No: 613 089 5718 • Mersis No: 0613080571800049

Ref.	Name
MCV0012	Med-Cover Barrier Cream Cloths
MCP0025	Med-Cover Barrier Cream Perineal Wipes
MCK0010	Med-Cover Wash Gloves with Barrier Cream
MCS0	Med-Cover Adjustable First Aid Pediatric Cervical Collar
MCI0	Med-Cover Adjustable First Aid Adult Cervical Collar
MCAB0010	Med-Cover Lemon Glycerin Swab Sticks
MCB0010	Med-Cover Barrier Cream(with Zinc Oxide) 100 gr Tube
MC0020	Med-Cover Barrier Cream Transparent 120 gr Tube
MCS0010	Med-Cover Barrier Film Spray 30 ml



EC DECLARATION OF CONFORMITY

MEDOFFICE SAĞLIK ENDÜSTRİ A.Ş

Yazıbaşı Mahallesi, Kuşçu Cad. no:9/1 Yazıbaşı, Torbalı
İZMİR/TURKEY

TEL: +90 232 431 31 12 **FAX:** +90 232 431 31 09 mail: info@medoffice.com.tr

PRODUCT(S): MED-COVER BARRIER CREAM CLOTHS
MED-COVER BARRIER CREAM PERINEAL WIPE
MED-COVER WASH GLOVES WITH BARRIER CREAM
MED-COVER LEMON GLYCERIN SWAB STICKS MOUTH CARE
MED-COVER BARRIER CREAM (WITH ZINC OXIDE) 100 GR TUBE
MED-COVER BARRIER CREAM TRANSPARENT 120 GR TUBE
MED-COVER BARRIER FILM SPRAY 30 ML
MED-COVER ADJUSTABLE FIRST AID PEDIATRIC CERVICAL COLLAR
MED-COVER ADJUSTABLE FIRST AID ADULT CERVICAL COLLAR

PRODUCT NUMBERS: 8681020477618, 8681020477045, 8681020477953, 8681020477632,
8681020477809, 8681020477816, 8683148050032, 8681020477458, 8681020477472

REFERENCE NUMBER: MCV0012, MCP0025, MCK0010, MCAB0010, MCB0010, MCB0020, MCS0010,
MCS0, MCIO

CLASSIFICATION: Class I MD (Non sterile and non-measuring)

CONFORMITY ASSESSMENT ROUTE: Annex V II of 93/42/EEC as amended by 2007/47/EC

We here declare that the above mention product meets the provisions of the council directive 93/42/EEC as amended by 2007/47/EC for medical devices incl. All supporting documentation is retained under the premises of the manufacturer.

PLACE, DATE OF ISSUE:

İZMİR 11.11.2019

SIGNATURE:

YÜCEL TEKER, GENERAL MANAGER


MEDOFFICE SAĞLIK ENDÜSTRİ ANONİM ŞİRKETİ
Yazıbaşı Mh. Kuşçu Cd. No: 9/1 Yazıbaşı Mahallesi / İZMİR
Tel: 0 (232) 431 31 12 • Fax: 0 (232) 431 31 09
www.medoffice.com.tr • info@medoffice.com.tr
Torbali V. D. No: 613 089 5718 • Mersis No: 0613029571800019