



EC Declaration of Conformity

issued in accordance with EC directive 2017/745 relating to

Medical Devices Regulation

Manufacturer: Zeyni Medical Tekstil Ins. San. Ve Tic. Ltd. Sti.

Adress: Yunus Emre Mah. 12. Yıldırım Sk. No:17 Yıldırım Bursa/ TURKEY

Commercial Name: Zeyni Medical

Product Name: Surgical Drapes & Surgical Gowns & Surgical Drape Sets

Classified as: Class I Sterile Medical Devices according to the 2017/745
Medical Device Regulation, Annex IX

Applied directives: 2017/745 Medical Device Regulation on medical devices, conformity assesment according to Annex VII

Applied Harmonized Standards: EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 14971:2012, EN ISO 15223-1:2016
EN 1041:2008+A1:2013, ISO 14155:2020, EN ISO 14155:2011, EN ISO 11607-1:2020, EN ISO 11607-2:2020 EN ISO 11717-1:2018
ISO 11737-2:2019, EN 556-1/AC:2006, EN ISO 11135:2014+A1:2019, EN ISO 10993-1:2018, EN ISO 10993-4:2017, EN ISO 10993-5:2009
EN ISO 10993-7:2008, EN ISO 10993-11:2018, EN62366-1:2015+A1:2020, EN 13795-2019, DIN EN ISO 9001:2015

Notified Body : UDEM ADRIATIC D.O.O
Radnicki cesta 54/R3, Green Gold Centar, IV. Kat. Zagreb CROATIA

Notified Body Number: CE 2696

Validity: 15.04.2027

The Company Zeyni Medical Tekstil Ins. San. Ve Tic. Ltd. Sti. Herewith declares that the above mentioned product meets all applicable provisions of the 2017/745 Medical Devices Regulation. The product is safe under prescribed and reasonably foreseeable conditions of storage and use. The company has implemented measures assuring that all the products of the mentioned type are safe and fulfil essential requirements of the 2017/745 Medical Devices Regulation. If the device is modified without the agreement of the undersign, this declaration become invalid in relation to the modified product.

Date of issue: 22.03.2022

Numan CAVDAR, President

On behalf of Company

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Yıldırım V.D. 998 141 1400 Tic Sic No 102917
Mersis No 0998141140000001

ZEYNI MEDİKAL TEKSTİL İNŞ. SANAYİ VE TİCARET LTD.ŞTİ.

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